3860

IRadimed CORPORATION

ADVANCED TECHNOLOGIES IN MR FLUID MANAGEMENT

MRidium™ MRI INFUSION/MONITOR SYSTEM

SERVICE MANUAL

REF 1125A

MRidium™ 3860+ Infusion/Monitor System

Service Manual, Part Number 1125A
Release 6B, 2015-08
ECN 000702

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SECTION 1
PREPARATION FOR USE

1.0 PREPARATION FOR USE

1.1 Introduction

This section contains information relative to the initial inspection and pre-operational checkout of the MRidium 3860+ Infusion Pump/Controller, the 3861 SideCar Secondary Pump and 3865 Remote Display/Charger. These procedures include a mechanical inspection, electrical inspection, pre-operational battery charge and a performance check to ensure that the instruments operate properly and have not been damaged during shipment or storage. The MRidium 3860's operating features are identified in the MRidium 3860+ Operation Manual (IRadimed PN 1138).

1.2 Pre-Operational Mechanical Inspection

The MRidium 3860+ and it's accessories have undergone thorough production control and quality assurance testing prior to shipment from Iradimed. The shipping container has been designed to protect the instruments against damage under normal shipping conditions; nevertheless, internal physical and/or electronic component damage could have occurred without leaving a visible signature. Therefore, it is recommended that the following inspection procedure be performed upon receipt of the instruments at the user's facility.

1. Carefully remove the **MRidium 3860+, 3861 or 3865** from their shipping containers. (It is recommended the shipping material be saved in the event an instrument has been damaged and must be returned to the factory for service or repair).
2. Inspect the exterior cases, front and rear, for holes, cracks, scratches, broken or damaged controls, missing components and/or screws.
3. Inspect the display window covering and overlay for scratches or cracks (3860+ or 3865).
4. Ensure the pumping chamber access door fits flush with the case at the top, bottom, and sides (3860+ or 3861).
5. Check the Door Handle/Eazy Latch lock for ease of operation and flush fit with door when latched (3860+ or 3861).
6. Inspect the pumping mechanism seal for damage and to ensure they are properly attached to the front case (3860+ or 3861).
7. Inspect the Bubble detector and Flo-Stop recess for damage or obstructions (3860+ or 3861).
8. Install an approved Iradimed administration set to ensure the Flo-Stop assembly seats correctly and the door closes and latches properly (3860+ or 3861).
9. Actuate each of the keypad controls on the front panel and ensure proper operation (see Section 1 of 1138 Operation Manual for location of controls) (3860+ or 3865).
10. Exercise the pole clamp mechanism to ensure freedom of movement (3860+ only).
11. Inspect the power cord for damage, bent prongs or deformed connector (3860+ or 3865).

12. Inspect AC Power/Charger Module and Power/Charger cable for physical damage and/or missing parts (3860+ only).

NOTE

In the event a MRidium 3860+, 3861 or 3865 shows evidence of shipping damage, notify the carrier's agent immediately. Do not return a damaged instrument to the factory before the carrier's agent has authorized repairs. Contact IRadimed for authorization to return the instrument for repair regardless of liability for repair costs.

1.3 Operational Performance Check

Prior to the first operational use and following any routine maintenance or servicing of the MRidium 3860+ and it's accessories, it is strongly recommended that an operational performance check be performed. The operational performance check consists of two phases; a Pre-operational Electrical Inspection to check the electrical integrity of the instrument for compliance with regulatory agency requirements and an Operational Performance Test to verify proper pump operation.

1.3.1 Pre-operational Check Battery Charge

Connect External DC Power/Charger (1120) power cord (1121) to AC Outlet, connect DC Charger cable from External DC Power/Charger (1120) to 3860+ pump DC input insuring connectors at both ends are screwed in tightly and allow the battery to charge for at least 6 hours.

1.3.2 Pre-operational Electrical Inspection

The pre-operational electrical inspection includes an electrical leakage test and a ground continuity check.

CAUTION

Some of these tests are inherently hazardous. Safeguards for personnel and property should be employed when conducting such tests. Tests should only be performed by qualified personnel.

1.3.2.1 Electrical Leakage Test

Connect power cord (1121) to safety analyzer. Connect ground cable from safety analyzer to the front chassis door latch clamp. Perform an electrical leakage current measurement in compliance with Underwriters Laboratories (UL) 2601 for Patient Care Equipment and / or IEC-60601-1. Leakage currents are to be less than 300 microamperes.

1.3.2.2 Electrical Ground Test

Connect External DC Power/Charger (1120) power cord (1121) to 25 Amp Ground tester, connect DC Charger cable from External DC Power/Charger (1120) to 3860+ pump DC input insuring connectors at both ends are screwed in tightly. Open pump door and connect alligator clip of chassis Ground wire from Ground tester to front chassis door latch pin and verify less than 0.1 ohms ground resistance and no fail test status.

1.4 Control and Indicator Operational Performance Test

The following operational performance test is designed to ensure each of the **MRidium 3860+'s** controls and indicators is functioning properly, and to check the operability of all the features available in the normal operating modes. These tests and associated procedures are presented in a sequence that provides an efficient, qualitative check of instrument operability.

Test Requirements

The following items of laboratory equipment and supplies are required to conduct the operational performance tests:

1. IRadimed 1056 administration set.
2. IV Solution Container.
3. Standard IV Pole.
4. Hemostat.
5. Empty fluid container.
6. Infutest 2000 (or equivalent)
7. Pronk Technologies OxSim, OX-1 SpO_2 Finger Simulator (or equivalent).

1.4.1 Power Indicator

Mount MRidium 3860+ on IV pole With External DC Power/Charger (1120) power cord (1121) to line power, DC Charger cable connected from External DC Power/Charger (1120) to 3860 pump DC input remove 1133 Battery Pack from Pump and verify LED below power on/off switches is illuminated Green. Reinstall 1133 Battery Pack and verify LED below power on/off switches is illuminated Yellow or Amber.

1.4.2 Initialization

Power on using overlay (IVP-0010) On (I) button. Verify the following initial display with current Software revision:

IRI LOADER FLASHER
© 201X
MS03 ”Day””Month””YR” HR:Min:Sec

MS01 ”Day””Month””YR” HR:Min:Sec

NO CARD DETECTED

followed by:

Powering On
X.X.XXXX
(X.X.XXXX = Current software revision)

followed by:

Normal pump display (Figure 1-1). Verify display is clear and readable.

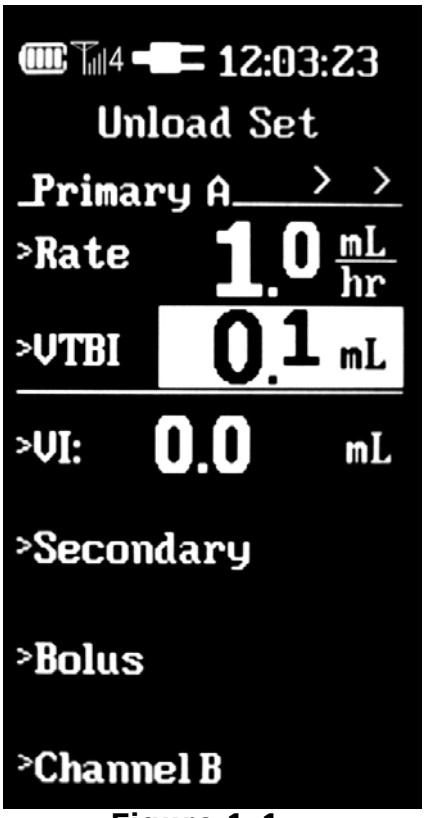


Figure 1-1.

1.4.3 Alarm Sound

Momentarily press the Off switch and verify Alarm sound. Pump should not turn off.

Verify Power Off requires 2 second depression of the O (off) key.

1.4.4 Prepare IV Set

Using IV Set 1056 insert set spike into water container and hang water container approximately 21 inches above MRidium 3860 MRI Infusion Pump. Squeeze drip chamber to fill approximately 2/3 full. With Free Flow Restrictor pinch clamp open prime tubing and clear air by slowly open roller clamp allowing water to fill tubing.

1.4.5 Install 1056 IV Set

Install 1056 IV Set in 3860+ Pump or 3861 SideCar as shown and close door (See Figure 1-2).

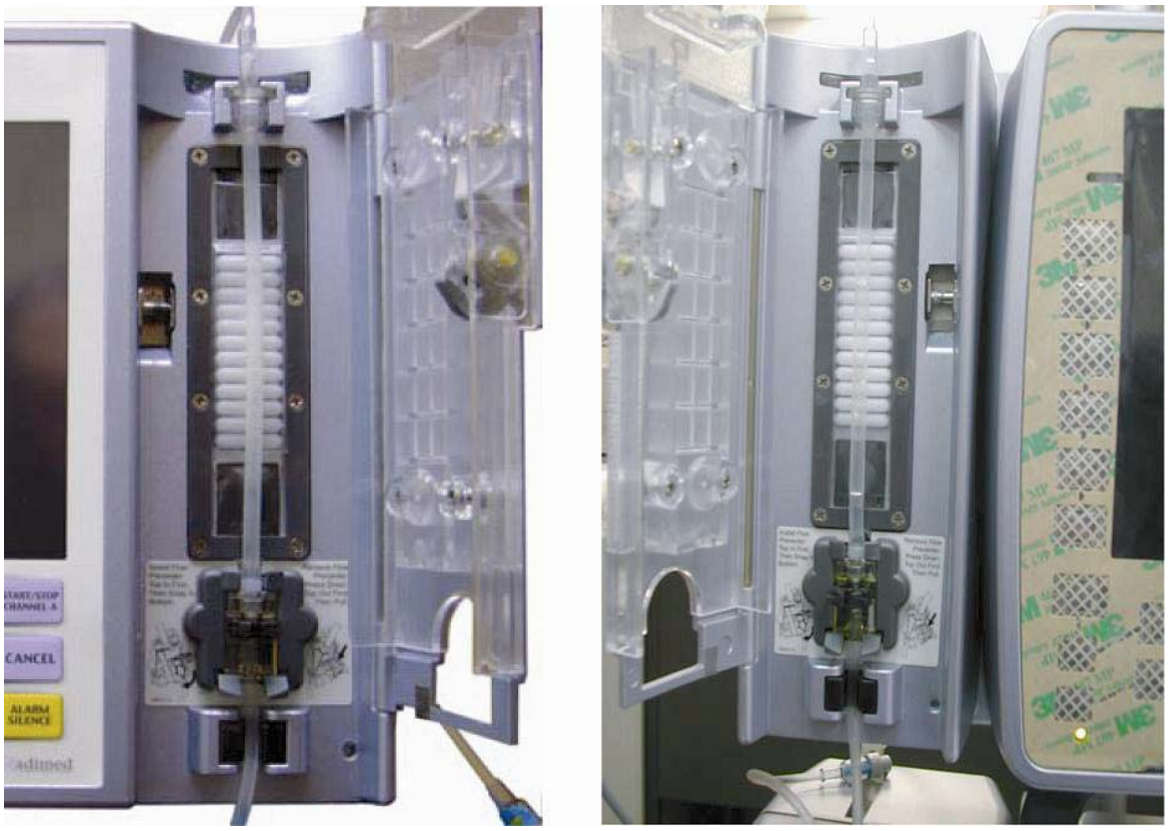


Figure 1-2.

1.4.6 Flow Test (3860+ or 3861 SideCar)

Connect patient end of IV Set to Infutest 2000 (or other IV Pump Flow test device). Set Pump Rate to 100 ml and VTBI to 25 ml, verify Ready to Start is flashing in lower right of the display. Press the Start/Stop Channel A (Channel B for SideCar) key and verify the pump begins running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the door.

Allow Test to run for a minimum of 10 minutes and verify "Ave.:" is 100.00 ml +/- 5%.

1.4.6.1 Alternate Flow Test

Connect patient end of IV Set to a graduated 50 ml cylinder with 0.1 ml resolution. Set Pump Rate to 100 ml and VTBI to 25 ml, verify Ready to Start is flashing in lower right of the display. Press the Start/Stop Channel A (Channel B for SideCar) key and verify the pump begins running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the door.

Press the Start/Stop Channel A (Channel B for SideCar) key when the pump completes the 25 ml and verify graduated cylinder contains 25 ml +/- 1.25 ml.

1.4.7 Inlet Occlusion Test

Press the Start/Stop Channel A (Channel B for SideCar) key and verify the pump begins running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the door. Use the hemostat to pinch off the tubing above the instrument and verify the following conditions:

1. Pump stops.
2. INLET OCCLUDED" Flashes in the upper portion of the screen.
3. Alarm audio – sounds.
4. Red bar alarm LEDs flashes.

1.4.8 Patient Occlusion Test

Clear occlusion (remove hemostat), then press the Start/Stop Channel A (Channel B for SideCar) key and verify the pump begins running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the door. Use the hemostat to close off the distal tubing and verify the following conditions

1. Pump stops.
2. "PATIENT OCCLUDED" Flashes in the upper portion of the screen.
3. Alarm audio – sounds.
4. Red bar alarm LEDs flashes.

Clear occlusion (remove hemostat), then press the Start/Stop Channel A (Channel B for SideCar) key and verify the pump begins running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the door

1.4.9 Bubble Detected (Air In Line) Test

Set Pump Rate to 500 ml and VTBI to 100 ml, verify Ready to Start is flashing in lower right of the display. Press the Start/Stop Channel A (Channel B for SideCar) key and verify the pump begins running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the door.

Tilt Drip Chamber below spike and allow a 0.75 (approximately 100 microliter) to 2 inch air bubble to enter line. Wait for air bubble to pass through pump and verify the following conditions:

1. Pump stops.
2. "Bubble Detected" Flashes in the upper portion of the screen.
3. Alarm audio – sounds.
4. Red bar alarm LEDs flashes.

NOTE

The Bubble Detector is located at the bottom of the pump and requires minimum of 100 microliter bubble to be detected. Repeat test if bubble brakes up before reaching Bubble Detector.

1.5 Radio Setup and Verification

See Section 1.1.3 and 1.1.6. of the 1138 MRidium™ 3860+ Operation Manual. Connect 2.4 GHz antenna and AC Power Cord to Remote Display Charger.

a. Turn both Pump and 3865 Remote Display/Charger on.

b. Press the Menu key on the Remote Display/Charger

c. Press the NEXT MENU soft key to bring up additional menu options, then press the Set Comm Channel soft key.

d. From the Radio Channel menu, select the desired Channel 1 through 6 by pressing the soft key next to that channel and verify that Channel is now highlighted.

e. Press the Menu key on the MRidium™ 3860+ MRI IV Pump.

f. Press the NEXT MENU soft key to bring up additional menu options, then press the Set Comm Channel soft key.

g. From the Radio Channel menu, select the same Channel that was selected for the Remote by pressing the soft key next to that channel and verify that Channel is now highlighted.

h. Add an ID marker on both the Remote and Pump with the Channel selected.

i. Verify communication between Remote and Pump by pressing the Menu key on one and the Cancel key on the other, and observing both display match and change simultaneously.

WARNING: Never Set two Pumps or Remotes on the same Comm Channel. Always confirm the remote display is communicating with the selected before use.

Note: the COMM channel number can be seen adjacent to the radio antenna icon on the front LCD display.

Troubleshooting aids for radio communication in very RF-tight MRI Magnet Rooms:

1) Channel selection - each of the 6 channels actually modify several communications parameters which provide a very wide range of RF link diversity. Please try different channels to find the best link.

2) Location - the 3865 Remote unit must be located close to the wall/window into the MR scanner room. It is recommended to be less than 3 feet away from the window. Do not allow people to get between the remote and pump, humans absorb large amounts of the 2.4 GHz frequency power of the link.

3) Adjust Radio Transmission power - IN the Service Mode, the radio power can be adjusted from medium power (+18 dBm is the standard factory setting) to high power (+24 dBm).

4) External Antenna - You can add an external antenna with longer cable which can be fixed directly on the viewing window. This can increase communication reliability in most all cases.

5) Space between Emitters - Make sure there is at least 0.5meters (20 inches) between the IRadimed equipment Antenna and any other radio emitters (e.g. monitors, injectors, etc.).

1.6 Programming Custom Drug Settings

1. Enter Service Mode. This is done by pressing the Power On (1) button while simultaneously holding the CANCEL key until the Service Mode MENU is observed on the screen.
2. Select the NEXT MENU Softkey 3 (F3), which will enter the extended MENU 3 choices.
3. On this MENU 3a, select Softkey 6 which will enter the next level of extended MENU 3b choices.
4. On this sub-MENU 3b you should see the following:
   - Flow Switch On (or Off)
   - Drug Table On (or Off)
   - Edit Custom Drugs
   - Clear Custom Drugs
   - <none>
   - Previous Menu
5. Verify that the Drug Table is enabled (ON). If it is not on, press Softkey 2 (F2) to turn on the Drug Table. Now all drug name choices will be available for programming.
6. When starting new, always select "Clear Customs Drugs" before beginning, which will ensure that the Drug Table has been reset to the factory default values. The factory default values can be seen in Table 1.

   Important: Do not select "Clear Custom Drugs" if any additions have been previously made to the Custom Drug Table, and you wish to retain these earlier settings. Selecting the new drug and/or parameter settings will add these values to your present Custom Settings. If you re-program any previously programmed custom drug and/or parameter setting, the most recent settings will be retained as the Custom Drug Settings.
7. This next choice is very important. The 3860 System allows the user to set the initial default drug that is presented in the Dose Rate Calculator (First Drug). By simply selecting and saving a drug name with its new user preset infusion parameters immediately after "Clear Custom Drugs", this first drug choice will be the initial drug seen when accessing the Dose Rate Calculator.
8. Select the EDIT CUSTOM DRUGS Softkey 3 (F3) on MENU 3b. This will present the standard Dose Rate Calculator Set-up screen. Select the First Drug choice by using the UP or DOWN keys to scroll through the 5 drug options (i.e. Drug?, Adenosine, Dobutamine, Propofol, or Dexmedetomidine). When the appropriate drug is seen, press the ENTER key to set the drug name.
9. Once the drug name has been selected, now select the drug modality to be programmed (i.e. Primary, or Bolus) by pressing the ENTER key.

   Important: The Secondary modality is provided in these options, but is not able to be programmed independently from the Primary settings. In the Normal Use mode, all Secondary infusions will use the either the factory default or the user-preset values from the Primary infusion parameters for the specific drug type.

10. Once the drug modality has been selected, now the DOSE, CONC (Concentration), or TIME (if applicable) values can be programmed. This can be accomplished by either using the ENTER key to scroll to the appropriate selection, or by pressing the appropriate Softkeys (either F1, F2, or F5) to select the DOSE, CONC, or TIME settings. The possible range of settings for each of these values can be found in the enclosed Table 3.
11. Set the DOSE numeric value using the UP/DOWN keys, or the numeric keypad keys. The numeric keypad keys include a decimal point, as well as a "Clear the number" function (the "C" key). Press ENTER once the numeric value has been selected.

    Important: Once these DOSE numeric values are set by the user, they become the initial staring points for a NEW PATIENT infusion in the Dose Rate Calculator. These numeric values can be modified during Normal Use mode. If the SAME PATIENT is selected by the user, the modified values are set in the Dose Rate Calculator. If a NEW PATIENT is selected, or the infusion pump has been turned off for more than 1 hour, the user-preset DOSE numeric values become the initial staring points for a NEW PATIENT infusion in the Dose Rate Calculator.

12. Set the DOSE units value using the UP/DOWN keys. Press ENTER once the numeric value has been selected. The choices for these values are:
    - mcg/kg/min
    - mg/kg/min
    - mcg/kg/hr
    - mg/kg/hr
    - mcg/kg
    - mg/kg
    - mcg/min
    - mg/min
    - mcg/hr
    - mg/hr

    Important: Once the DOSE unit values are set by the user, they can't be modified during Normal Use mode, as they will remain fixed to the user-preset values. The only way to modify these DOSE units will be to re-enter the Service Mode and re-program these units.

    With Software version 3.0.xxxx and higher, the expanded Drug Library choices for the 5 drug types and DERS Drug Library include the additional choices:

    - mg
    - mcg
    - mU/kg/min*
    - Units/kg/hr*
    - mU/kg/hr*
    - Units/min*
    - Units/hr*
    - mU/hr*
    - mU/min*

- Units*
- mU*
- Units/kg*
- mU/kg*

*With Software version 3.2.9 and higher, when selecting the units-based Dose Units values, the Concentration Units Value must first to set to either "units", or "mU".

With Software version 3.2.9 and higher, the default Bolus Dose units for the Drug Library choices for the 5 drug types, and DERS Drug Library includes the following choice:

- mL (NOTE: The "mL" selection is available as a Dose unit choice. Additionally, the Bolus Dose feature now includes the Factory Default to be "0 mL" with a Time of "1 Minute" for the 5 drug types).

13. Now select the CONC (Concentration) numeric numerator values by either using the ENTER key to scroll to the CONC selection, or by pressing the appropriate Softkey (F2) to select the CONC setting. Set the CONC numeric value using the UP/DOWN keys, or the numeric keypad keys. The numeric keypad keys include a decimal point, as well as a "Clear the number" function (the "C" key). Press ENTER once the numeric value has been selected.
14. Set the CONC numerator units value using the UP/DOWN keys. Press ENTER once the numeric value has been selected. The choices for these values are:

    - mcg
    - mg

    With Software version 3.0.xxxx and higher, the expanded Drug Library choices for the 5 drug types and DERS Drug Library include the additional choices:

    - units
    - mU (milli-units)

    With Software version 3.2.9 and higher, when selecting the units-based Dose Units values, the Concentration Units Value must first to set to either "units", or "mU".

15. Now select the CONC (Concentration) numeric denominator value by either using the ENTER or F2 key to scroll to the CONC selection. Set the CONC numeric value using the UP/DOWN keys, or the numeric keypad keys. The numeric keypad keys include a decimal point, as well as a "Clear the number" function (the "C" key). Press ENTER once the numeric value has been selected.

    Important: Once these CONC numeric values are set by the user, they become the initial staring points for all infusions for this drug type in the Dose Rate Calculator. These numeric values can be modified during Normal Use mode. If the SAME PATIENT is selected by the user, the modified values are set in the Dose Rate Calculator. If a NEW PATIENT is selected, or the infusion pump has been turned off for more than 1 hour, the user-preset CONC numeric values become the initial staring points for a NEW PATIENT infusion in the Dose Rate Calculator.

NOTE: The CONC denominator units value is always in milliliters (mL) and can't be modified.

16. If any timeless DOSE units have been set (e.g. mcg/kg or mg/kg), the TIME value can be set using the UP/DOWN keys, or the numeric keypad keys. The numeric keypad keys include a "Clear the number" function (the "C" key). Press ENTER once the numeric value has been selected.
17. Save all the user-preset value by pressing the SAVE DRUG Softkey (F6). The set up screen will now return to MENU 3a. Select.

    Important: During the drug programming, entries can be made into the WEIGHT, RATE, AND VTBI areas, but these values are not saved as user-presets. They are only made available to allow the user to check the entry values are within the acceptable limits of the various parameters. In Normal Use mode, these values will reset to zero (0) until set by the user prior to the infusion.
18. The set up screen will now return to MENU 3a. Select the NEXT MENU Softkey (F6) to access the Custom Drug set-up choices.
19. On this sub-MENU 3b you should see the following:
    - Flow Switch On (or Off)
    - Drug Table On (or Off)
    - Edit Custom Drugs
    - Clear Custom Drugs
    - <none>
    - Previous Menu
20. Repeat the programming process, beginning at Step 8 above, and select the next drug type, drug modality, and appropriate DOSE, CONC, and TIME (if applicable), and then again press SAVE DRUG.

    Important: During the drug programming, always press the SAVE DRUG Softkey (F6) after each group of user-preset values have been entered (e.g. first group - Adenosine/Primary, second group -Adenosine/Bolus, third group -Dobutamine/Primary, fourth group - Dobutamine/Bolus, etc.). If SAVE DRUG is not pressed, the user-preset values will not be retained, and either the prior settings, or factory default settings will be used for this drug type in the Dose Rate Calculator.
21. Complete the programming process cycling through Steps 8 through 17 above until all user-reset values have been saved. For the user's convenience, a table for retaining the user-presets number in enclosed in Table 2, and can be photocopied for multiple uses to record each MRidium's Pumps user settings.

Note: If the DRUG? Drug type is programmed by the user for a custom drug not listed in the MRidium Pump's default drug name list (e.g. adrenaline), then these custom settings are saved, the DRUG? Label in the Dose Rate Calculator will be changed to CUSTOM to denote another drug type has been entered. Record this custom drug name in Table 2, and it is recommended to add a label to the MRidium pump identifying this custom drug type for all operator's to see before initiating an infusion using these parameters.

22. If only 1 or 2 drug types are programmed by the user, the remaining drug types will continue to show the factory default values in the Normal Use mode of the Dose Rate Calculator. These default values can be found in enclosed Table 1.

23. After all the user-presets have been entered and saved, the Pump can be shut off by pressing the Power Off (0) key.

24. Turn on the Pump by pressing the Power On (1) button. Access the Dose Rate Calculator as described in the Operator's Manual, and now confirm the user-preset values have been correctly entered. It is recommended to set-up a test IV set and initiate a brief (1 to 10 second duration) infusion for each user-preset drug type and modality to confirm proper operation before returning the pump to clinical use.

25. If any problems occur during the programming of the user-preset values, or the user-preset values need to be canceled or erased, the CLEAR CUSTOM DRUGS softkey can be pressed at any time to reset all Dose rate Calculator back to the factory default values found in Table 1.

26. Another feature available in the Service Mode Dose Rate Calculator set-up is the additional options available with the use of the DRUG TABLE OFF choice. There are four optional modes of operation:

    - One, if the DRUG TABLE is turned OFF before any Custom Drug settings have been entered and saved, only the DRUG? Drug type with the factory default settings will be available in the Normal Use mode. All numeric and units values can be modified when used in this manner.
    - Two, if the DRUG TABLE is turned ON before any Custom Drug settings have been entered and saved, all Drug types with the either the user-preset factory default settings will be available in the Normal Use mode. All numeric values can be modified when used in this manner, but the units values for any user-preset values can't be modified when used in this manner (as described above in Step 12).
    - Three, if the DRUG TABLE is turned ON, programmed by the user, and then turned off after the Custom Drug settings have been entered and saved, only the First-Drug Drug type with the user-preset values will be available in the Normal Use mode. All numeric values for this single drug type can be modified when used in this manner, but the units values for any user-preset values can't be modified when used in this manner (as described above in Step 12).
    - Four, if the DRUG TABLE is turned OFF after the CLEAR CUSTOM DRUGS key has been pressed, only the DRUG? Drug type with the factory default settings will be available in the Normal Use mode. All numeric and units values can be modified when used in this manner.

27. If any user-preset values are modified, or new drug types or modalities are added to the original programmed set of parameters, always record the updated user-presets values and added drug types or modalities in a new copy of Table 2 for the MRidium Pump's user settings. Again, it is recommended to set-up a test IV set and initiate a brief (1 to 10 second duration) infusion for each user-preset drug type and modality to confirm proper operation before returning the pump to clinical use.

28. As an added feature, the customized user-preset values can be duplicated and transferred to other pump(s). To do this, perform the following steps:

1. Complete setting the user-presets as described in Steps 1 through 27 above, and verify user-presets have been saved.

2. Turn off the 3860 Pump.

3. Using another AM05 Software Update card provided by Iradimed Corporation, install this card in the 3860 Pump's Memory Port in the rear of the pump.

4. Press the Power On (1) button while simultaneously holding the F6 key (bottom key on the left side of the display). Continue holding the F6 key until the messages "BURNING CARD, FLASHING MSTR, FLASHED: 1%, 2%, 3% …" is observed on the screen. The F6 key can now be released. The process will automatically complete and display "FLASHING SUCCESSFUL".

5. When "FLASHING SUCCESSFUL", turn off the 3860 Pump. The pump will not re-start automatically after completing this process.

6. When complete, load this AM05 Software Update card into the second pump, and when uploading is completed, power the pump OFF/ ON, and then confirm the customized user-preset values have been duplicated and transferred to the second pump.

7. Repeat Step 6 above for any other pump(s) that require these customized user-preset values.

Dose Rate Calculator Factory Default Values
Table 1

Drug Name	Label	Factory Defaults		
		DRC Default Values		
		Primary	Secondary	Bolus
Drug?	Dose	0.0 mcg/kg/min	Same as Primary	0.0 mcg/kg/min
	Conc	1.00 mg/ 1 ml	Same as Primary	1.00 mg/ 1 ml
	Wt.	0.0 kg	Same as Primary	0.0 kg
	Rate	UND mL/hr	Same as Primary	UND mL/hr
	Time	None	None	None
	VTBI	0.0 mL	Same as Primary	0.0 mL
Adenosine	Dose	0.0 mcg/kg	Same as Primary	0.0 mcg/kg
	Conc	3.00 mg/ 1 ml	Same as Primary	3.00 mg/ 1 ml
	Wt.	0.0 kg	Same as Primary	0.0 kg
	Rate	UND mL/hr	Same as Primary	UND mL/hr
	Time	6 minutes	Same as Primary	1 minute
	VTBI	0.0 mL	Same as Primary	0.0 mL
Dobutamine	Dose	0.0 mcg/kg/min	Same as Primary	0.0 mcg/kg/min
	Conc	1.00 mg/ 1 ml	Same as Primary	1.00 mg/ 1 ml
	Wt.	0.0 kg	Same as Primary	0.0 kg
	Rate	UND mL/hr	Same as Primary	UND mL/hr
	Time	None	None	None
	VTBI	0.0 mL	Same as Primary	0.0 mL
Propofol	Dose	0.0 mcg/kg/min	Same as Primary	0.0 mg/kg
	Conc	10.0 mg/ 1 ml	Same as Primary	10.0 mg/ 1 ml
	Wt.	0.0 kg	Same as Primary	0.0 kg
	Rate	UND mL/hr	Same as Primary	UND mL/hr
	Time	None	None	1 minute
	VTBI	0.0 mL	Same as Primary	0.0 mL
Dexmedetomidine	Dose	0.0 mcg/kg/hr	Same as Primary	0.0 mcg/kg
	Conc	4.00 mcg/ 1 ml	Same as Primary	4.00 mcg/ 1 ml
	Wt.	0.0 kg	Same as Primary	0.0 kg
	Rate	UND mL/hr	Same as Primary	UND mL/hr
	Time	None	None	10 minutes
	VTBI	0.0 mL	Same as Primary	0.0 mL

Note: The values of "UND" in this table denotes an "UNDer-range" value.

Warning: The Factory Default values are provided for initial setup only. Numbers other than zero (0) are used in the table to avoid division by zero (0). Verify all selections prior to beginning the infusion.

Note: The secondary infusion feature is not available when starting an infusion with the Dose Rate Calculator with pump software version 3.0.xxxx or higher. Additionally the Bolus dose factory default is "0 mL" with a time of "1 minute".

Dose Rate Calculator Custom Protocol Values Worksheet
Table 2

Custom Protocol(s)					
Set 1st	Drug Name	Label	DRC User Selected Custom Values		
			Primary	Secondary	Bolus
	Custom:	Dose		Same as Primary	
		Conc		Same as Primary	
	Name:	Wt.		Same as Primary	
		Rate		Same as Primary	
		Time		Same as Primary	
		VTBI		Same as Primary	
	Adenosine	Dose		Same as Primary	
		Conc		Same as Primary	
		Wt.		Same as Primary	
		Rate		Same as Primary	
		Time		Same as Primary	
		VTBI		Same as Primary	
	Dobutamine	Dose		Same as Primary	
		Conc		Same as Primary	
		Wt.		Same as Primary	
		Rate		Same as Primary	
		Time		Same as Primary	
		VTBI		Same as Primary	
	Propofol	Dose		Same as Primary	
		Conc		Same as Primary	
		Wt.		Same as Primary	
		Rate		Same as Primary	
		Time		Same as Primary	
		VTBI		Same as Primary	
	Dexmedetomidine	Dose		Same as Primary	
		Conc		Same as Primary	
		Wt.		Same as Primary	
		Rate		Same as Primary	
		Time		Same as Primary	
		VTBI		Same as Primary	

MRidium Infusion Pump Serial Number:_____

Note: Retain a copy of this Worksheet with Service Records for future use and/or changes.

Note: The Custom Drug Protocol values are those programmed by the user in the Service Mode. If no values are programmed by the user, the Factory Default values are used in the Dose Rate Calculator.

Important: The First Custom Drug Protocol selected and saved after clearing the Custom Drug Settings will be set as the new default drug when the Dose Rate Calculator is first selected in the Normal Use mode. It will also be the only drug choice, if the drug Table is turned off after the Custom Drug have been set by the user.

Warning: The Factory Default values are provided for initial setup only. Numbers other than zero (0) are used in the table to avoid division by zero (0). Verify all selections prior to beginning the infusion.

Table 3

STANDARD USER SETTING RANGES AND DEFAULTS		
Characteristic	**Specification Range**	**Initial Start-Up (Factory Default) Value**
Primary Flow Rate Range - 0 to 100 mL/hr	0.1 to 99.9 mL/hr in 0.1 mL/hr increments	1 mL/hr
Primary Flow Rate Range - > 100 mL/hr	100 to 1400 mL/hr in 1 mL/hr increments	1 mL/hr
Secondary Flow Rate Range - 0 to 100 mL/hr	0.1 to 99.9 mL/hr in 0.1 mL/hr increments, 100 to 1400 mL/hr in 1mL increments.	0.1 mL/hr
Primary Volume To Be Infused (VTBI) Range	0.1 to 999 mL	0 mL
Secondary Volume To Be Infused (VTBI) Range	0.1 to 999 mL	0 mL
Total Volume Infused (VI) Range	0.1 to 9999 mL	0 mL
Keep Vein Open (KVO) Rate Range	adjustable, 0 to 5 mL/hr, in 1 mL/hr increments; 0 denotes KVO is off.	1 mL/hr
Bolus Rate Range	0.1 to 99.9, 100 TO 1400 mL/hr in 1 mL/hr increments	500 mL/hr
Bolus To Be Infused Range	0.1 to 999 mL	0 mL
Occlusion Pressure Limit Range	1 to 10 PSI	None, always retains last setting.
Dose Programming - Patient Weight Range	0.1 to 160 Kg in 0.1 Kg increments	0.0 Kg
Dose Programming - Drug Concentration Range	0.1 to 99.9 mg/mL	Varies, dependent on selected Drug.
Dose Programming CONC - Diluent Range	1 to 999 mL	1 mL
Dose Programming - Dose in mg/Kg/min Range	0.1 to 9999 mg	0.0 mg
Dose Programming - Volume to Be Infused	0.1 to 999 mL	0 mL
Dose Programming - Time Range	1 to 99 min; 0.1 to 99.9 min (Software version 3.0.xxxx and higher)	Varies, dependent on selected Drug.
Alarm Sound Volume	> 65 dBA at 1 meter, Settings = Minimum to Maximum (Graphical Display)	None, always retains last setting.
Drug Library Option	Allows selection of 1 of 5 drugs used in Dose Rate Calculator. When OFF, only one drug (Drug?) is available.	Default value is on. (Drug Library choices are available)

Additional Dose Rate Calculator Settings and Ranges
(for use with Dose Rate Calculator and Dose Error Reduction System (DERS))
Table 3

Units Value	Minimum	Default	Maximum	Notes
Dose				
mcg/kg/min	0.01	0	9,999	(a)
mg/kg/min	0.01	0	9,999	(a)
mcg/kg/hr	0.01	0	9,999	(a)
mg/kg/hr	0.01	0	9,999	(a)
mcg/kg	0.01	0	9,999	(a)
mg/kg	0.01	0	9,999	(a)
mcg/min	0.01	0	9,999	(a)
mg/min	0.01	0	9,999	(a)
mcg/hr	0.01	0	9,999	(a)
mg/hr	0.01	0	9,999	(a)
mg	0.01	0	9,999	(b)
mcg	0.01	0	9,999	(b)
mL	0.1	0	999	(c)
mU/kg/min	1	0	99,999	(b) (d)
Units/kg/hr	1	0	99,999	(b) (d)
mU/kg/hr	1	0	99,999	(b) (d)
Units/min	1	0	99,999	(b) (d)
Units/hr	1	0	99,999	(b) (d)
mU/hr	1	0	99,999	(b) (d)
mU/min	1	0	99,999	(b) (d)
Units	1	0	99,999	(b) (d)
mU	1	0	99,999	(b) (d)
Units/kg	1	0	99,999	(b) (d)
mU/kg	1	0	99,999	(b) (d)

Units Value	Minimum	Default*	Maximum	Notes
Concentration				
mg	0.01	1	9,999	(a)
mcg	0.01	None	9,999	(a)
Units	1	1	25,000	(b)
mU	1	None	25,000	(b)
mL	1	1	999	(a)

IMPORTANT: When using DERS, the actual use range will vary dependent on hospital-set limits. Consult Facility Drug Library control personnel for specifc details.

* With the Factory Default drug library, the Concentration default numeric values will match those found in Table 1 in Appendix A for these 5 drug types.

NOTES:

(a) Standard Drug Library choices for the 5 drug types.

(b) With Software version 3.0.xxxx and higher, the expanded Drug Library choices for the 5 drug types and DERS Drug Library.

(c) With Software version 3.2.9 and higher, the "mL" selection is available as a Dose unit choice. Additionally, the Bolus Dose feature now includes the Factory Default to be "0 mL" with a Time of "1 Minute" for the 5 drug types.

(d) With Software version 3.2.9 and higher, when selecting the units-based Dose Units values, the Concentration Units Value must first to set to either "units", or "mU".

1.7 MRidium™ 3860+ MR IV Pump

DOSE ERROR REDUCTION SYSTEM (DERS), OPTION

Part Number 1145 - Drug Protocol Programming

1 Introduction

The Model 3860+ MRI Infusion System can be expanded to include an optional Dose Error Reductions System (DERS) feature (PN 1145) that allows user facilities the ability create a unique Drug Library of user specified drug names, and also to establish nominal values and limits for the Dose, Concentration, Weight and Time, creating custom infusion protocols.

The DERS option provides the following features:

• A user programmable drug library memory card for storage of the specific infusion protocols established by the hospital facility. This library is accessed using the pump's Dose Rate Calculator Menu.

• The drug library card supports up to 30 separate user-programmed infusion protocols for either primary and/or primary/bolus infusions, retrievable by drug/protocol name.

• User-programmed nominal starting values for: Dose, Concentration, Time.

• User-programmed **Hard** limits (maximum and minimum) and **Soft** limits (high and low limits that require a user confirmation to exceed) for: Dose, Time, and patient Weight. (Concentration may not be changed by users)

• Status indicators denoting when the Drug Library ('LIB') is active, and when infusion protocol parameters are operating outside designated "soft limits". These limits are programmed by the user as the 'soft' high and low limits that require a user confirmation to exceed.

• The infusion's Dose is displayed on the running display screen, and can be adjusted directly (titrated) on the running screen (Dose Mode display).

• Remaining Time for an active infusion is displayed on the running screen.

2 Installation

NOTE: The optional Dose Error Reductions System (DERS) feature requires MRidium 3860 Pump software version 3.0.xxxx or higher. Refer to the Installation instructions in the PN 1145 DERS Software Update Kit's SD005 Instructions for loading the pump software (if necessary), and installing the DERS Drug Library Card.

3 Programming the DERS Library Card

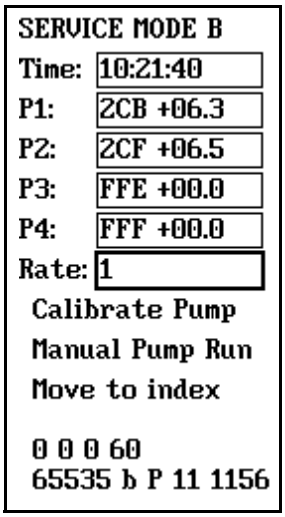
Before beginning the actual programming of a DERS memory card, it is highly recommended, that the list of drug names to be used and their associated protocol parameters such as 'Dose', units to applied, and any Hard or Soft limits for each infusion type (Primary and Bolus) be prepared and thoroughly reviewed. The 1145 kit supplies you with a blank Xcel spreadsheet which can be used to assist in the preparation of the DERS library. Use this sheet or other suitable method to gather and review the drug protocols to be used.

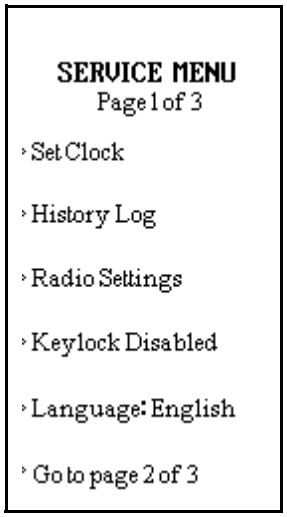
The DERS card maintains the order of drugs/protocols as entered (they cannot be re-sorted by the pump). Drug names can be the entire width of the display screen, and so, may be up to twenty characters long. However, various Tall/Capital and wide letters/numbers can limit the total character count. The spreadsheet contains a legend of valid numeric ranges and types if units available. Appendix A of the Operation Manual also shows these ranges. Transfer of the drug protocols into the DERS memory card is done via the following manual steps. Protocols cannot be electronically sent into the pump/DERS card. Note: as a minimum each drug entered into the DERS library must contain a drug name, the units of the DOSE, and complete drug concentration information consisting of the units and dilution values of the concentration.

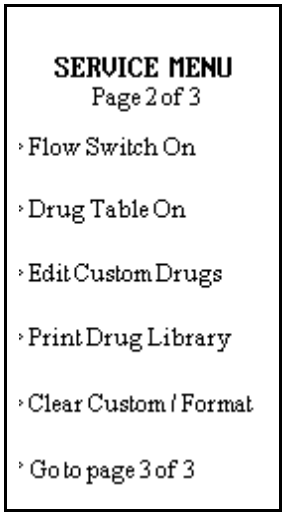
1.7.1 Preparing the Pump and DERS memory for programming.

Enter **SERVICE MODE**, Choose service mode options by pressing 'F3' (third function key down left side of display), move to page 2 of the options by pressing 'F6'.

When beginning the programming of a new DERS memory card – insert the DERS memory card into the SD memory slot on the rear panel. Choose the option "Clear Custom/ Format" by pressing the 'F5' key. This DERS memory card is now ready to be programmed.







1.7.2 Programming / Adding Drug Names and Protocols

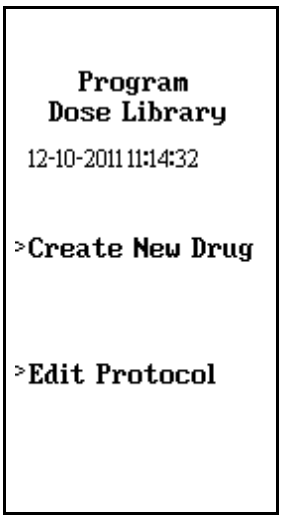
Enter **SERVICE MODE**, choose service options by pressing 'F3' select EDIT CUSTOM DRUGS by pressing 'F3', and see:

'PROGRAM DOSE LIBRARY' display

Select **Create New Drug** by pressing 'F2' to add new drug names to the DERS memory card.

Select

Edit Protocol by pressing 'F4' to enter or change the dosing protocol of a named drug.



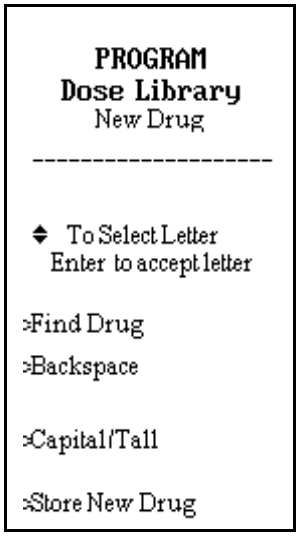
1.7.3 Create New Drug

Upon selection of this option, verify the display shows "PROGRAM DOSE LIBRARY" "New Drug".

Notice twenty place holding dash marks across upper portion of display. These indicate remaining space for drug name characters. Drug names must be no wider than this display screen.

Create drug names by choosing each letter/number with the up/down arrow keys. Press ENTER to select a character and move to the next selection. When drug name is complete, press 'F6', 'Store New Drug' name, saving the name to the DERS memory.

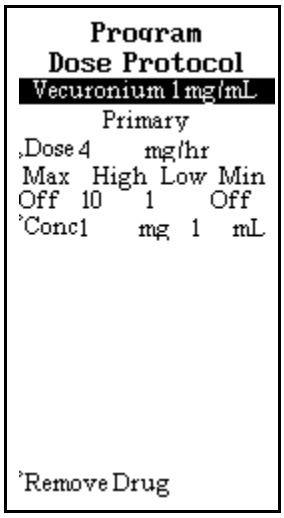
Note, capital/Tall letters as shifted with the 'F5' key and 'F4' is backspace to correct entries.

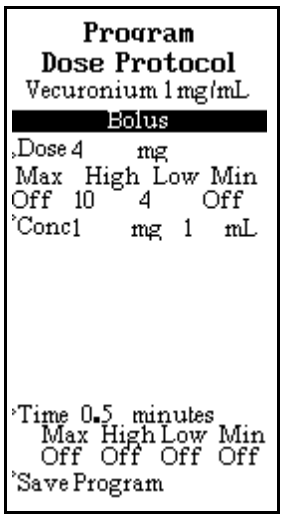


1.7.4 Programming or Editing a Dose Protocol

1. It is recommended to choose and set the units for concentration as the first step, as this will limit the range of unit choices for the Dose. Units are available in a number of weight/time combination for both mass (mg/mcg) and international UNITS (Units/mU).
   Select Concentration pressing the 'F2" adjacent the 'Conc' label. Select each numeric value and unit type with the numeric keys and up/down arrow keys. Press ENTER to save each entry field and advance to the next.
2. Set desired DOSE value and units in a similar manor, using the numeric and up/down arrow keys. Choose the DOSE entry by pressing 'F'. ENTER will accept each entry and move the highlight cursor to the next entry field.
   The line directly below the DOSE value and Unit line permits the entry of the hard and soft limits for DOSE. With the highlighted cursor just below 'MAX', enter the numeric value of any hard maximum limit for DOSE desired. Pressing enter accepts this limit and moves the highlight to the next. Enter limit values for the soft 'High' limit, soft 'Low' limit and hard 'MIN' limit as desired.
   (High and Low are soft limits which may be overridden by the user confirmation, MAX and MIN are *hard* limits which cannot be exceeded)
3. Set patient weight limits in a similar mannor as above. Select Weight by pressing the 'F3' key, pressing ENTER to select and highlight each limit for numeric entry. Again, limits can be entered for MAX, High, Low, and MIN weights in kilograms.
4. Time may be a user selectable input for some types of Dose units, in which case limits for the Time of Dose delivery are also available and settable in a similar mannor as above. Select Time limits by pressing 'F5' and ENTER till the limits are highlighted. Set MAX, High, Low, and MIN as above.
5. Review and validate the data input on the display screen and make corrections as needed.
6. **Save Program -** 'F6' will save the protocol as programed with the associated named drug. This key serves also to 'Remove Drug', pressing ENTER, moving highlight cursor position can be used to toggle between 'Save Program' and 'Remove Drug'. Make certain 'F6' label shows 'Save Program' when intending to save a drug protocol**.**
7. To set up a dosing protocol for Bolus delivery, verify drug name, press ENTER highlighting the current Dose mode (eg. Primary), use up/down arrow to find BOLUS mode, press ENTER to select. Repeat steps 2-6 above.

Press CANCEL, and return to "PROGRAM DOSE LIBRARY", **a.** above to enter any additional Drugs/protocols.





1.7.5 Removing Drugs

Via the 'Edit Custom Drug' to 'Edit Protocol' menu, previously saved drugs can be removed from a DERS Library memory card.
Enter **SERVICE MODE**, choose service options by pressing 'F3' select EDIT CUSTOM DRUGS by pressing 'F3', and see:

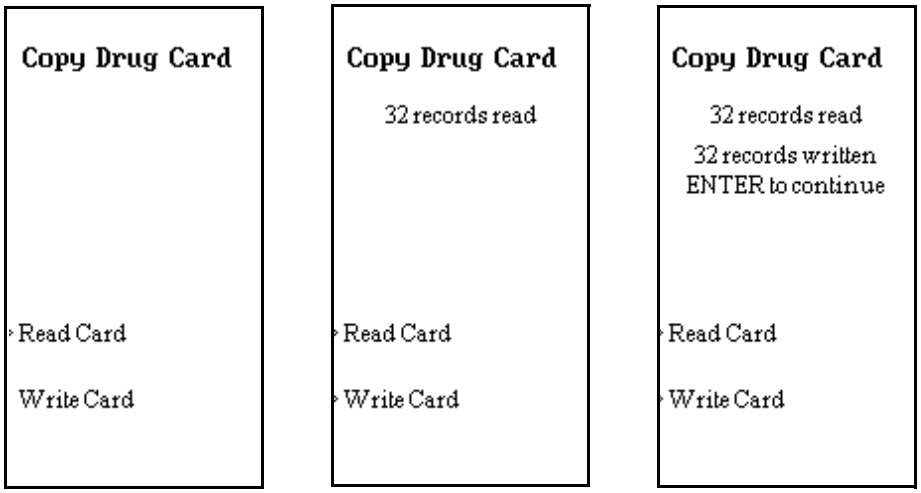
'PROGRAM DOSE LIBRARY' display

Select **Edit Protocol** by pressing 'F4' see the Program Dose Protocol display with the first drug name from the DERS library highlighted. Select the drug name to be removed by scrolling through each drug name with the up/down keys. Notice that 'Remove Drug' appears next to the 'F6' key. Pressing 'F6' will remove the highlighted drug name and protocol from the DERS memory card.

1.7.6 Copy DERS Drug Library card (cloning cards)

DERS memory card may be copied for use in multiple 3860 MR IV pump installations. To make copies of a DERS card:
Enter **SERVICE MODE** , Choose service mode options by pressing 'F3' (third function key down left side of display), move to page 3 of the options by pressing 'F6' twice. Select 'Copy Drug Card' by pressing 'F2'. Insert DERS card to read a validated drug library to be copied, into the SD slot on the rear panel of the 3860+ MR IV pump.
Press 'Read Card' – 'F2' The drug library of this card will be temporarily stored into the pump for copying. The display will show the number of drug read form the card.
Insert a new or erased formatted DERS card into the SD memory slot. Select 'Write Card – 'F5' Drug library will be written to the new DERS card. The

process of making additional copies can be repeated by simply inserting another new or erased formatted DERS card and pressing 'F5'.
The DERS cards should now be installed into 3860+ MR IV pumps following the ***Installing or Removing DERS Library programming card*** procedure below.



1.7.7 Erasing DERS Memory Cards

DERS cards which have been previously had drugs 'SAVED' to them, may be erased and prepared for re-use. To Erase: Insert DERS card to be erased into the SD memory slot on the rear of the pump.

Enter **SERVICE MODE** , Choose service mode options by pressing 'F3' (third function key down left side of display), move to page 3 of the options by pressing 'F6' twice. Select 'Erase Drug Card' by pressing 'F1', then ERASE CARD pressing 'F4'. The DERS card may now be re-used, to store a new DERS library.

Installing or Removing DERS Library programming card: (to be done by Biomed), (to be performed outside the MRI Magnet Room)

a. Remove the small poly bag from the 1145 update kit which contains the Black Aluminum SD Card retainer clip and the #4 screw. This part will be used as a safety guard once the programming card is in place.

IMPORTANT: *The hardware provided is non-magnetic. Do not substitute any parts (clip or screw), as these parts may be magnetic, and not safe for use in the MRI.*

b. With power OFF, insert the programmed AM05 MRidium™ DERS Library Card into the Memory Port on the back of the pump. Insert with the card label facing DOWN (diagonal cut corner of the card facing RIGHT).

c. With AM05 card in place, using a Phillips head screw driver, place the SD Card Retainer clip directly over the card, aligning with screw hole to left of SD card slot. A small tang on the right side of the clip should align inside the right edge of the card slot. Secure the screw. This will prevent accidental removal of card during use.Pulse Oximeter Verification (3860+ only).

1.8 Pulse Oximeter Verification (3860+ only)

See Section 7 of the 1138 MRidium™ 3860+ **Operation Manual.**

a. Plug 1170 Fiber Optic Sensor Cable into port on back of 3860+ pump.

b. Turn on 3860+ Pump.

c. Place sensor on operator using 1171 grip. Verify normal operator's SpO_2 and Pulse reading, SpO_2 display is 96 - 100%, Pulse display is pulse rate of operator, and no error messages are displayed (Low Quality, Noise, ect.) are displayed on pumps LCD display. (See Figure 1-3 below).

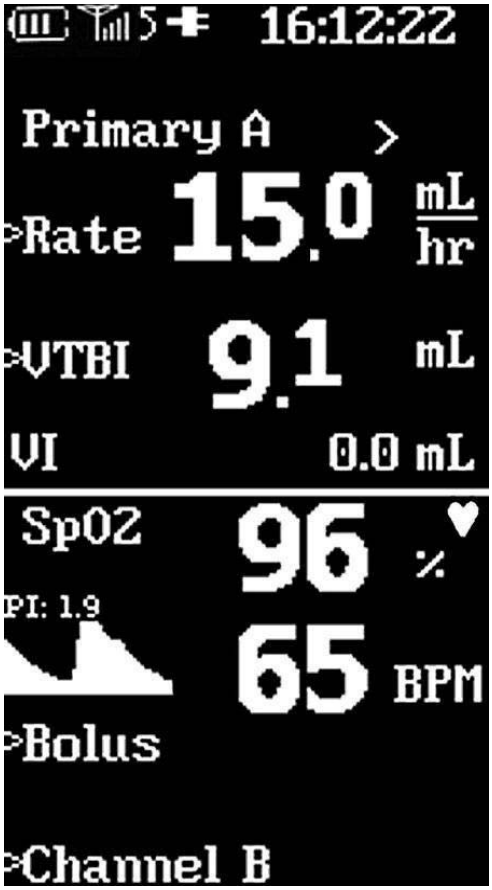


Figure 1-3.

d. Remove sensor grip from operator finger and watch for "Probe Off" alarm. Silence the alarm. SpO_2 display window will appear with bars and no readings until sensor is re-attched to operator.

e. Unplug Sensor Cable from rear of pump and watch for "No Probe" alarm. Silence the alarm and SpO_2 display area will leave the screen.

MRidium 3860+
PREPARATION FOR USE
TEST DATA SHEET

Pump Serial No. _____ Software Revision _____

Date _____ Technician _____

Test No.	Description	Reference Paragraph	Pass/Fail
1	Pre-Operation Mechanical Inspection	1.2	Pass___Fail___
2	Battery Charge	1.3.1	Pass___Fail___
3	Electrical Leakage Test	1.3.2.1	Pass___Fail___
4	Electrical Ground Test	1.3.2.2	Pass___Fail___
5	Control and Indicator Operational Performance Test	1.4	Pass___Fail___
6	Power Indicator	1.4.1	Pass___Fail___
7	Initialization	1.4.2	Pass___Fail___
8	Power Key Alarm Sound	1.4.3	Pass___Fail___
9	Flow Test	1.4.6	Pass___Fail___
10	Inlet Occluded	1.4.7	Pass___Fail___
11	Patient Occluded	1.4.8	Pass___Fail___
12	Bubble Detected (Air-In-Line)	1.4.9	Pass___Fail___
13	Remote Radio Verification	1.5	Pass___Fail___
14	Pulse Oximeter Verification (3860+ only)	1.8	Pass___Fail___

SECTION 2
SERVICE MODE DESCRIPTION

2.0 SERVICE MODE DESCRIPTION

The MRidium 3860+ is configured with a Service Mode that allows technicians to access the software diagnostic subsystem. Once the Service Mode is enabled, the technician can use the diagnostic test sequences to verify operation of the operator interface features, to operate the pumping mechanisms independent of the alarm/malfunction interrupts, to check Analog to Digital voltages and to access the history log. Additionally, the Service Mode is used to test the serial port, configure the instrument's radio communication interface and select one of the six available languages for the user interface presentations (when available).

Put Pump into Service Mode by Press overlay KeyPad On (I) button and the holding the overlay KeyPad Cancel key depressed until the Service Mode is displayed. Once enabled, Maintenance Mode operation is strictly software dependent.

The Channel B Start/Stop key changes the pump from SERVICE MODE A (main 3860+ pump) to SERVICE MODE B (3861 SideCar pump).

2.1 Service Mode Display

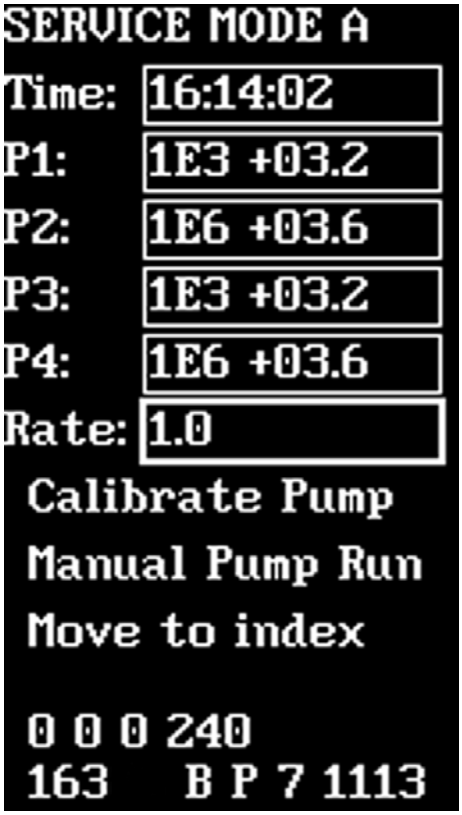


Figure 2-1.

The initial Service Mode A screen (see Figure 2-1) displays current time, P1 pressure sensor located directly above the pump mechanism for inlet pressure/occlusion sensing for pump channel A, and P2 located below the pump mechanism for patient side fluid pressure sensing of pump channel A, if the side-car is installed P3 pressure sensor located directly above the pump

mechanism for inlet pressure/occlusion sensing for pump channel B, and P4 located below the pump mechanism for patient side fluid pressure sensing of pump channel B; Sensor A to D count is displayed on the left with pressure in psi displayed on the right of each location. These are non-selectable information displays.

Selections from the Service Mode screen are Rate, Calibrate Pump, Manual Pump Run, and Move to Index. The initial selection is Rate, from this selection the Up and Down keys are used to change the Rate, Enter key is used to set the selected Rate, and Start/Stop Channel A key. "Calibrate Pump" is used for initial pump calibration and requires a Sartorius GD603 scale connected to the pumps I/O port, and is used to find the pumps index offset point (typically for factory use only). "Manual Pump Run" when selected and the enter key is pressed commands the pump to run at a constant speed and is used for motor tuning. "Move to index" when selected and the Enter key is pressed, commands the pump to move to index (beginning of pump cycle).

The top row of numerics at the bottom of the screen are defined as follows. the first position displays motor speed in RPMs, the second position is for display of the scale weight value when connected to the Sartorius GD603 scale, and the third position is for display of the various completion and error codes when using the Sartorius GD603 scale for calibration.

The fourth position shows the motor counter timer, which decrements from 1000 to 0 as the motor rotates. When the motor is stopped, the counter timer is set to 240 (as shown). Whenever the motor is started, or the flow rate is changed, the counter timer is rest to 1000.

The bottom row of alpha-numerics are defined as follows:

16383 - On initial entry to the to the Service Mode screen this area will display 16383, once the pump has been commanded to move it will display the current position of the encoder wheel.

B - "B" equals bubble detected or air in line at bubble detector, "b" equals no bubble detected.

P - "P" equals Line power is detected, "p" equals no line power detected.

7 - This numeric is currently for factory use only.

1151 - This numeric is a display of the regulated 11V power supply, (1151 = 11.51V).

2.1.1 Calibrate Pump Screen

Figure 2-2.

From the Service Mode screen the Calibrate Pump A or B Screen (see Figure 2-2) is accessed by pressing the F1 (top function key on the left side of the display screen). This screen is for displaying current pump A or SideCar B calibration settings, adjusting these settings, clearing the History record and making pressure sensor adjustments.

NOTE

The Delay setting should be recorded for future reference should a repair action cause loss of this Delay setting. This Delay setting is found during factory calibration with the pump connected to a high accuracy calibrated scale (Sartorius GD603) while the delivery profile at 1 ml/Hr is studied by internal calibration software. Anytime the mechanical alignment of the encoder wheel relative to the pumping finger position is changed or suspect (pump block or motor replaced), this calibration process must be performed.

1. **Delay and Comp.** Use the enter key to move from Delay and Comp and the up or down arrows followed by the Enter key to change these settings (see above NOTE). The Comp is adjustable from +8.0% to -8.0% and is used to adjust pump flow accuracy.
2. **Clear History.** Pressing this soft key (F3) just to the right of the Clear History option will delete the current history record. Note: the history record can be downloaded to a PC using the History Log soft key (F2) in the SERVICE MENU described below.
3. **Tare Offset.** Pressing this soft key (F4) just to the right of the Tare Offset option will Zero the pressure sensors. Note: These sensors must be zeroed with IV set tubing in place without fluid (or fluid level at center of pump).

4. **Span Cal.** Pressing this soft key (F5) just to the right of the Span Cal option will set the Span of the pressure sensors. The software assumes 5 psi is applied to the pressure sensors. Note: To ensure pressure has been applied the software looks for an A to D count of 455 to 485 as displayed in the Service Mode in the left numerics beside P1 & P2.

2.1.2 Battery Status Screen.

The Battery Status is brought up by pressing the F2 soft key (second key down on left side of screen) from the SERVICE MODE screen.

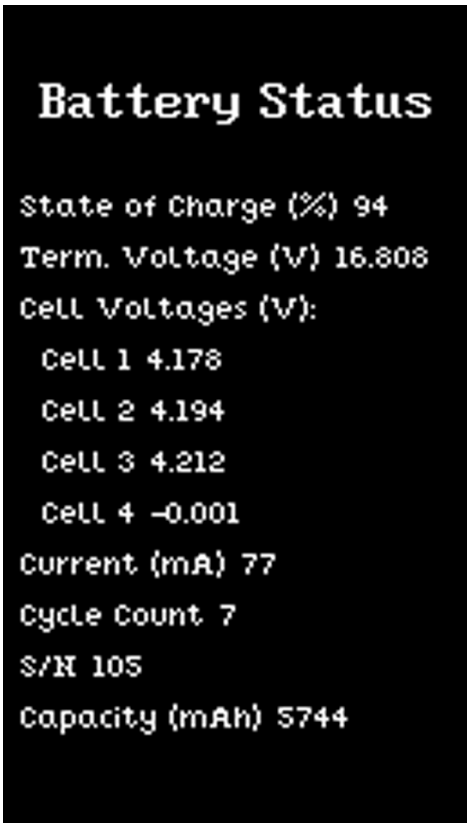


Figure 2-3.

2.1.2.1 Battery Status

The Battery Status screen (see Figure 2-3) displays the State of Charge, Terminal Voltage, each of the 4 Cell voltages, current in milliamps, cycle count, and battery serial number.

2.1.3 Service Menu Screen

Figure 2-4.

The SERVICE MENU (see Figure 2-4) is brought up by pressing the F3 soft key (third key down on left side of screen). From this menu the Set Time, History Log, Radio Settings, Keylock, Language and a Next Menu are accessible.

2.1.3.1 Set Clock.

Pressing the Set Clock soft key (F1) just to the right of the Set Clock option in the SERVICE MENU will select the Set Clock menu with Hour highlighted (see Figure 2-5).

Use the up and down arrow keys to change the hour, then press Enter key to set the Hour and move to minute selection. Repeat this process for each selection. The soft key (F2 & F3) may be used to access Time or Date directly. Press the CANCEL key to exit this menu.

Figure 2-5.

2.1.3.2 History Log.

Pressing the History Log soft key (F2) just to the right of the History Log in the SERVICE MENU will select the History Log (see Figure 2-6) for output to the rear I/O port. The screen will display Press ENTER to stop and the pump will start sent a text history log out the I/O port.

Before selecting this menu option, the pump must be connected to a PC with a standard RS232 cable (no connection on pins 1,6,8,9;2-2,3-3,4-4,5-5 & 7-7) and a terminal program running ready to receive. Set your terminal program as follows:

Baud rate: 1200.
Data: 7 bit.
Parity: none.
Stop: 1 bit.
Flow Control: none.

NOTE

"Tera Term Pro" has been included in the Calibration Software folder of this Service Manual CD.

The following table describes this history log output.

Token	Description	Format	Event
1	Power On	SW Revision string	At power up
3	KVO Rate changed	#.# mL / hr	
4	Occlusion Pressure Alarm Limit (downstream) changed	# PSI	
5	Alarm Volume Limit changed	# (no units)	
7	Dose Error Reduction Soft Limit Over-ride	Refer to Table 6	
8	Dose Error Reduction Hard Limit Over-ride	Refer to Table 6	
10	Infusion Rate	#.# mL/hr, P or PT #.# mL/hr, S or ST #.# mL/hr, K or KT #.# mL/hr, B or BT	Only when Primary (P), Secondary (S), KVO mode (K) or a Bolus (B) for channels A or B is started or after titration (T) is confirmed
11	Volume to be infused	#.# mL, P or PT #.# mL, S or ST #.# mL, K or KT #.# mL, B or BT	Only when Primary, Secondary, KVO mode or a Bolus for channels A or B is started or after titration is confirmed
12	Volume infused	#.# mL, P #.# mL, S #.# mL, K #.# mL, B #.# mL	Only when Primary, Secondary, KVO mode or a Bolus for channels A or B is started, after titration is confirmed, or the VI is cleared.

Token	Description	Format	Event
14	Stop infusion button pressed	#.# mL	Store VI
15	Cancel infusion button pressed	#.# mL	Store VI
17	Alert Detected	Alert number. See table 4	
18	Hold time exceeded alarm		
22	Pump door open has just been opened		
23	Pump Malfunction	Error number See error number Table 2.	
29	Time or date was changed	Time when set time screen was exited	
39	History data corrupted		
40	On Battery, or on AC Power	Switch to AC power or Start/Switch on Battery power.	AC = AC Power B = Battery Power
49	Audible alarm silenced	Alarm Code See Table 3.	
50	Alarm Detected	Alarm Code. See Table 3.	
67	Power Off -with power switch		
68	Power Off - without power switch (AC power or Battery failure)		
79	Pressure Unstable		
81	Program Lost - re-enter settings		
83	Service mode activated		Service screen has been entered
87	Dose rate program – Weight (0.1 kg – 999.9 kg)	#.# kg	When started from the DRC screen.
88	Dose rate program – Dose (0.001 – 999.900)	0.001 mcg/kg/min, or 0.001 mg/kg/min, or 0.001 mg/kg/hr	When started from the DRC screen. Store the appropriate units with the dose value.
89	Dose rate program – Concentration (0 – 99.990)	0.001 mg	When started from the DRC screen.
90	Dose rate program – Dilute (1- 999)	1 mL	When started from the DRC screen.
91	Dose rate program – Rate	0.1 ml/hr	When started from the DRC screen.
92	Dose rate program – VTBI	0.1 ml	When started from the DRC screen.
93	Dose rate program – Drug	Drug index. See table 5.	When started from the DRC screen.
94	Dose rate program – Time	99 min.	When started from the DRC screen.
95	Recheck Settings		0 = Primary 1 = Secondary 2 = Bolus

Token	Description	Format	Event
100	History Checksum Error		At power up when a checksum error has been encountered.
101	History database has been cleared.		When history log is manually cleared.
102	Remote Comm. Established		
103	Remote Comm. Lost		

Table 2 : Error number descriptions.

Token	Action Description	Event
1	Master / Slave communications failure	Channel A
2	Watchdog timeout	
3	Motor control processor watchdog timeout	Channel A
4	Nonmaskable interrupt	
5	ROM checksum error	
101	Master / Slave communications failure	Channel B
103	Motor control processor watchdog timeout	Channel B
129	Slave processor did not see encoder index while seeking starting index mark	Channel A
130	Motor is rotating too slow.	Channel A
132	Starting index mark found in wrong position relative to minor index marks.	Channel A
134	Should have seen a minor index mark and has not.	Channel A
135	Should have seen a minor index mark while the motor is not running and has not seen a minor index mark.	Channel A
136	Slave processor did not see encoder index during normal operation	Channel A
229	Slave processor did not see encoder index while seeking starting index mark	Channel B
230	Motor is rotating too slow.	Channel B
232	Starting index mark found in wrong position relative to minor index marks.	Channel B
234	Should have seen a minor index mark and has not.	Channel B
235	Should have seen a minor index mark while the motor is not running and has not seen a minor index mark.	Channel B
236	Slave processor did not see encoder index during normal operation	Channel B
1000	shaft revolution occurred in less than the required amount of time	Channel A
1001	Shaft revolution should have occurred but did not.	Channel A
1002	Shaft revolution timeout error	Channel A
1003	Shaft should not be turning but it is turning.	Channel A
1100	shaft revolution occurred in less than the required amount of time	Channel B
1101	Shaft revolution should have occurred but did not.	Channel B
1102	Shaft revolution timeout error	Channel B
1103	Shaft should not be turning but it is turning.	Channel B

Table 3: Alarm codes for events 49 (Audible alarm silenced) and 50 (Alarm detected)

0	Door Open
1	Patient Occlusion
2	Bubble Detected
3	Bag Empty
4	Upstream Occlusion
5	Dead Battery
6	Clear VI
7	Check Door (possible Free-Flow conditions)
8	Invalid Parameter

Table 4: Alert codes for event 17

Token	Action Description	Format
0	Battery depleted alert - Low Battery - one shot warning at 15% capacity.	
1	Battery depleted alert - Very Low Battery - recurring warning at <5% capacity.	
2	Battery depleted alert - Bad Battery - running on battery power but unable to communicate with it.	
3	SpO2 Alert - Low SpO2	
4	SpO2 Alert - Low HR	
5	SpO2 Alert - High HR	
6	SpO2 Alert - SpO2 Inop	
7	SpO2 Alert - Bad SpO2 Probe	
8	SpO2 Alert - No Probe (Off Pump)	
9	SpO2 Delayed Alert - Probe Off (Patient)	

Table 5: Drug codes

0	Drug? (no specific drug defined)
1	Adenosine
2	Dobutamine
3	Propofol
4	Dexmedetomidine

Table 6: Dose Error Reduction Codes

Token	Action Description	Format
BD-	Bolus/Dose - Below Limit	
BD+	Bolus/Dose - Above Limit	
BT-	Bolus/Time - Below Limit	
BT+	Bolus/Time - Above Limit	
PD-	Primary/Dose - Below Limit	
PD+	Primary/Dose - Above Limit	
PT-	Primary/Time - Below Limit	
PT+	Primary/Time - Above Limit	
PW-	Primary/Weight - Below Limit	
PW+	Primary/Weight - Above Limit	

2.1.3.3 Radio Settings

Pressing the Radio Settings soft key (F3) just to the right of the Radio Settings option in the SERVICE MENU will select the Configure Radio menu sp highlighted (see Figure 2-7).

Figure 2-6.

2.1.3.3.1 WIT2450 Banner

When a WIT2450 Radio is connected to the pump and this menu is selected the WIT2450 banner "WIT v1.32 Cirronet
:Remote 0003087 for detailed information of radio settings download the WIT2450 Integration Guide from www.cirronet.com.

2.1.3.3.2 Command:

Use the Command soft key (F1) to switch from command to setting, then UP and Down arrow keys select commands or change settings.

2.1.3.3.3 Send Command

This soft function key (F4) is used to send the selected command and setting to the WIT2450 radio. Rec: and Sent: will display the result when this function is used.

2.1.3.3.4 Store

This soft function key (F5) is used to store any radio setting changes. When selected Rec: and Sent: will display "m" indicating changes have been stored in the radio.

2.1.3.3.5 Load Defaults

This soft function key (F6) is used to automatically send all Iradimed default radio settings to the radio. Once Load Defaults is complete, the Store (F5) soft function key must be pressed to store default settings.

From the normal operating screen, Menu, Next Menu, and Set Comm Channel the radio setting for channel selection are automatically changed. The Radio setting changes are as follows:

Channel 1 - Wn = 06, Ph = 90

Channel 2 - Wn = 07, Ph = 91

Channel 3 - Wn = 08, Ph = 92

Channel 4 - Wn = 09, Ph = 93

Channel 5 - Wn = 10, Ph = 94

Channel 6 - Wn = 11, Ph = 95

2.1.3.3.6 Radio Power Levels

Each pump ships from the factory with a default setting of 63 mW (+18 dBm) and at this level will penetrate most MRI magnet screen rooms. Some MRI magnet screen rooms are shielded tight enough to require the maximum power level setting of 250 mw (+24 dBm).

To increase the power level to maximum change command "wp" from 01 to 02.

Table 1: Radio Configuration Sheet

Command	Description	Pump	Remote
sp [00, 14]	Set Protocol Mode	00	00
wb [0, 1, 2, 3]	Set Transceiver Mode	0 (remote)	1 (base)
wd [ ]	Set Default Handle	00	00
wl [00, ff]	Set Lockout Key	00	00
wn [00, 3f]	Set Hopping Pattern	06	06
wg [0, 1, 2]	Enable Global Network Modes	00	00
wp [0, 1, 2]	Set Transmit Power **See note 1**	01	01
wr [?]	Received Signal Strength	*read only[*00,ff*]*	N / A
wu	Set point-to-point direct mode	01	01
pe [0, b]	Set Alternative Frequency Band **See note 2**	01	01
ph[00, fe]	Set Hop Duration	90	90
pl [?]	Get Maximum Data Length	*read only*	N / A

Table 1: Radio Configuration Sheet

Command	Description	Pump	Remote
pn [01, 3e]	Set Maximum Number of Remotes	08	08
pk [00, d4]	Set Minimum Data Length	01	01
pr [00, ff]	Set Packet Attempts Limit	08	08
pt [00, ff]	Set Data Transmit Delay	00	00
pv	Set Slot Assignment	00	00
pw [00, 2f]	Set Base Slot Size	08	08
px	Set ARQ Mode	00	00
zb [0, 1]	Banner Display Disable	01	01
zc [0, 1, 2]	Set Escape Sequence Mode	01	01
zh	Factory Serial Number - High Byte	*read only*	*read only*
zm	Factory Serial Number - Mid Byte	*read only*	*read only*
zl	Factory Serial Number - Low Byte	*read only*	*read only*
zp	Set Duty Cycle	00	00
zq	Enable Low Power Acquisition	00	00

Note 1 : 0 = 10 mW / 10 dBm, 1 = 63 mW / 18 dBm, 2 = 250 mW / 24 dBm

Note 2 : (2431.3 – 2474.5 MHz) Avoids 802.11b bands 1 & 2

2.1.3.4 Keylock Enable

Pressing the Keylock soft key (F4) just to the right of the Keylock option in the SERVICE MENU will enable or disable the keylock menu option in the normal pump operator menu screen. (see Figure 2-8)

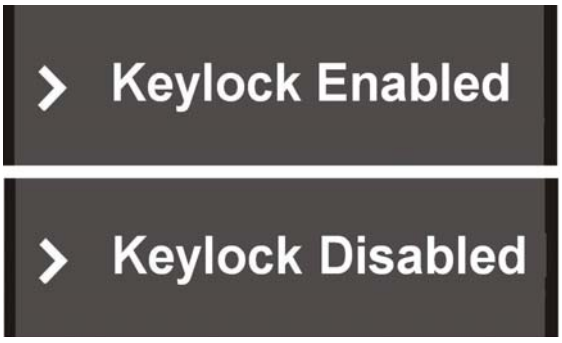


Figure 2-7.

2.1.3.5 Language Option

On the 3860+MRidium 3860+ pump, pressing the Language soft key (F5) will enable the user to scroll through the various languages available for use on the MRidium 3860+ screen display. Once the selected language is set in the Service Menu, exit the Service Mode. On next power-up of pump, selected language will be displayed.

2.1.3.6 Next Menu

Pressing the Next Menu soft key (F6) will change the display screen to the second Service Menu option page (See Figue 2-9).

Figure 2-8.

2.1.3.7 Flow Switch On

For MRidium™ 3860+ Pump's, Flow Switch On should be displayed as the first item on the screen.

2.1.3.8 Drug Table On

For MRidium 3860+ pumps, the Dose Rate Caculation table can be turned ON or OFF by pressing the soft key next to Drug Table (see Figure 2-8).

2.1.3.9 Edit Custom Drugs

For MRidium 3860+ pumps, the Edit Custom Drugs menu allows user to program custom drug settings in the Dose Rate Caculator Set-up Screen (see Section 1.6 for instructions on programming custom drug settings).

2.1.3.10 Clear Custom Drugs

For MRidium 3860+ pumps, the Clear Custom Drugs softkey allows user to reset the Drug Table to the factory defaults (see Section 1.6 for instructions on Clear Custom Drugs softkey).

2.1.3.11 Previous Menu

Pressing this soft key will return the user to the first Service Menu screen.

SECTION 3

PREVENTIVE MAINTENANCE AND SYSTEMS TEST

3.0 PREVENTIVE MAINTENANCE

3.1 Introduction

This section contains preventive maintenance instructions, service mode operating procedures, troubleshooting routines, disassembly and reassembly procedures and a comprehensive operational performance test for the **MRidium 3860+, 3861 and 3865** MR IV pump and accessories. Please reference Section 5 for drawings and exploded views of the various assemblies, components, and PCB's.

This section provides detailed system test and verification steps as well as a complete discussion of preventive maintenance (PM) procedures. The individual technician will be well served to create an appropriate level of PM procedures pulling from those contained below, for their institution using their own judgment and historical processes applicable for other types of IV pump PM's as currently being performed, ie: electrical safety, IV pump flow testing and the like. PM procedures which are significant and/or unique to the mRidium MR IV pump are described in section 3.2, and should become part of any institutional specific PM process.

CAUTION

Printed circuit board assemblies (PCBA's) are easily damaged when integrated circuits are removed and replaced. Excessive heat applied to the circuit board traces and pads can cause delamination of the metal foil and base material. Damage of that type is essentially irreparable; therefore, only low-temperature soldering irons and vacuum solder removal tools should be used when removing and replacing components on PCBA's. Leads on integrated circuit components should be cut before attempting to un-solder and remove.

In addition CMOS devices are sensitive to static electrical charges and may be damaged during repair if the repair activity is not performed in an ESD protected environment using approved ESD protective procedures.

3.2 Preventive Maintenance

The **MRidium 3860+** Infusion Pump/Controller, **3861** SideCar Secondary Pump and **3865** Remote Display/Charger are designed and assembled with the goal of minimizing maintenance requirements. The integral microprocessor of the 3860+ incorporates a diagnostic routine that monitors the instrument's subsystems and operating parameters. Detection of operating system irregularities or failures that affect the instrument's functional operation activates audio and visual Alarms or Malfunction alerts for operator notification. Problems of this nature are recorded in the non-volatile RAM history log for subsequent use by technical personnel in performing troubleshooting and repair actions.

Maintenance-free operation between regularly scheduled preventive maintenance inspections can be enhanced by performing routine cleaning on an as required basis. The recommended interval for preventive maintenance inspections is once a year based on normal use and operation. Verification of proper

instrument operation is the responsibility of the user. At the user's option, routine testing and verification may be performed at the factory for a nominal cost. The following paragraphs describe in detail the procedures for performing general maintenance requirements on the **MRidium 3860+**, **3861** and **3865.**

Preventative maintenance (PM) may be performed with the 'basic' tools shown in section 3.2.3, should a PM reveal issues requiring further service steps more tools such as those shown in 3.4.2 may be required. Additionally, a review and understanding of Section 1 of this manual should accompany the instructions of this PM section

3.2.1 Cleaning Instructions

CAUTION

DO NOT SPRAY the instrument with any fluids. DO NOT immerse or stand the instrument in any fluids. Always unplug the AC power cord before cleaning. DO NOT attempt to sterilize with Ethylene Oxide gas, head steam, radiation, or autoclaving. To do so may damage the pump and void the warranty.

1. Exterior surfaces of the **MRidium 3860+, 3861** and **3865** may be cleaned using any of the following recommended solutions. This list is considered adequate to permit clean up of all expected contaminates.
2. Isopropyl alcohol Warm soapy water Household Bleach (10% solution, i.e. 1 part household bleach to 9 parts water)
3. These solutions may be applied using a soft, lint free cloth; a soft bristle brush and/or a cotton swab. Once the contamination has been removed, a cloth soaked with fresh water should be used to rinse the entire instrument removing and diluting all of the residual cleaning solution. Then the entire instrument surface should be completely rinsed using another cloth thoroughly moistened with fresh water. Following the fresh water rinses the instrument must be thoroughly dried with a soft, lint free cloth.

WARNING: Prior to reattaching the AC power cord to the power/charger, ensure the male base of the power input module is clean of any electrolyte and thoroughly dry. Check the female contacts on the power cord for contamination; if contaminated, replace the power cord.

3.2.2 Mechanical Inspection

Perform the following mechanical inspection:

1. Inspect the urethane pumping gasket/seal (IVP1070) for excessive wear and/or holes annually or after 1000 hours of instrument operating time. If damaged or worn, replace the seal (3860+ and 3861).

2. Perform a pumping mechanism integrity /extension spring (HM10) integrity test by closing the IV set patient side tube clamp while the pump is operating in the Pump mode. (Any iRadimed Series 1000 IV set may be used for this test) Set the occlusion pressure to maximum at 10 PSI. If the springs are not pulling the pumping 'fingers' tightly enough over the IV set tube to maintain proper closure or 'pinch off' of the tubing, or there is another failure resulting in weak 'pinch off', the channel will not reach occlusion pressure due to back flow leakage. This may manifest also a 'free flow' of IV fluids into an attached patient. Reference the 3860+ MR Infusion Pump Assembly drawing on page 5-4 and inspect the pump assembly. This basic test should be done <u>any time</u> service has been performed as well as for all PM's.
3. Inspect the exterior case, front and rear, for holes, cracks, scratches, spilling, broken or damaged controls, missing components and/or screws (3860+ and 3861). Carefully inspect the areas where the hinge pin passes through the chassis and door for any signs of cracking or excessive wear or corrosion.
4. Inspect the displays for scratches or cracks, missing dots or other readability problems (3860+ and 3865).
5. Ensure the pumping chamber door (AS112 or AS113) fits flush with the case at the top, bottom, and sides (3860+ and 3861), and can be latched securely closed. Ensure the pumping chamber door opens and closes freely without any friction or resistance. Verify the retaining screw at the bottom of the pumping chamber door axle is securing in place. Verify the brass pumping chamber door axle is free of any corrosion or material that prevents free movement of the pumping chamber door.
6. Check the door handle/cam (AS112 or AS113 to AS104) lock for ease of operation and flush fit with door when latched (3860+ and 3861). When open, check that the clamp handle is held up at approximately a 45 degree angle to the door and releases smoothly as the door touches the chassis face upon closing, with the clamp releasing and moving downward smoothly.
7. Inspect the bubble detector (HE09/HE09A) and test its ability to detect fluid. Install an IV set with no fluid into the pump and run at a rate of 10ml/Hr. The pump should indicate Air In Line and alarm within 50 seconds. Note: the pump software must 'see' a tube with fluid to pass the power on bubble detector test to allow further pump operation. Simply place a small segment of tubing with fluid into the bubble detector if prompted to " Remove Set" to satisfy this bubble detector power on test.
8. Inspect the Flo-Stop holder (3860+IVP1047/AS120) recess for damage, obstructions, or fluid spillage. Some drugs can attack the plastic and weaken the materials, replace this part as needed. The IV set should remain seated within the Flo-Stop holder when the door is opened and no "Check Door" alarm should occur. (3860+ and 3861).
9. Inspect upper door clamp latch paw (IVP1038) for damage or wear.
10. Install an iRadimed 1056 administration set primed and flushed with water, ensure the Flo-Stop assembly seats correctly and the door closes and latches properly (3860+ and 3861). Set must remain seated as door clamp is opened and flow stop slide of the IV set is pulled out to the flow close position.
11. Actuate each of the keypad controls on the front panel to ensure proper operation (3860+ and 3865)(see Figure 3-1 in the 1138 Operation Manual for location of controls).

12. Exercise the pole clamp mechanism to ensure freedom of movement (3860+).
13. Set the pump to deliver 100 mL/Hr and check for accurate fluid delivery. Follow the procedures below utilizing the 'Infutest' or alternate calibrated fluid measurement system.
14. Replace the CR2032 coin cell memory/clock 'backup' battery every two years or as needed. (Failing backup batteries result in loss of proper time keeping and history records and may produce a "Lost History" message.

3.2.3 Basic Tools (For basic repairs and PM's) *

#1 Phillips Screw Driver

#2 Phillips Screw Driver

PH00 Phillips

9/64" Allen Driver or T Bar

3 mm Allen Driver or T Bar

3/16" Nut Driver

100 mL and/or 25 mL Graduated cylinder (Simple flow testing)

MRidium IV sets

MRidium IV sets Pressure gauge (0 to 10 psi) and pressure means (ie: hand bulb) with modified IVP1056 IV set. (See Figure 1 below paragraph 3.2.4.2.4)

3.2.4 3860+ PM Service Mode Verification

Reference the Section 2 Service Mode description. Service Mode is accessed by pressing the overlay KeyPad On (I) button and the holding the overlay KeyPad Cancel key depressed until the service Mode is displayed. Note, the following procedure is the same for both 3860+ Pump (Service Mode A) and 3861 SideCar (Service Mode B).

3.2.4.1 Motor Speed Verification

Select MANUAL PUMP RUN, press and hold ENTER on Keypad (100% duty cycle). Verify speed to approximately 135 +/-30 RPM..

3.2.4.2 Pressure Verification

3.2.4.2.1 Tare Offset Verification:

Connect Pressure Gauge with Hand Bulb to a circular IV Test Set (no fluid) and with Hand Bulb open (0 PSI) See photo below. Open Door, Load IV Test Set, Close the Door and verify pump moves to index, press the F1 key, then press the F4 key (Tare Offset). Press the Cancel key to return to the Service Mode display and verify P1 and P2 are 0 +/- 0.5.

3.2.4.2.2 Pressure Verification

Close Pressure Gauge Hand Bulb and apply 5.0 PSI per Pressure Gauge. Verify P1 and P2 displays 5 +/- 0.5.

3.2.4.2.3 Pressure Adjustment

If P1 and P2 did not display 5 +/- 0.5, ensure

pressure gauge remains at 5.0, press the F1 Key (top left white key) to enter the Calibrate Pump screen, then press the F5 key (Span Cal). Press the Cancel key to return to the Service Mode display and verify P1 and P2 are now 5 +/- 0.5.

3.2.4.2.4 Zero Verification after Adjustment

Open pressure gauge hand bulb and verify P1 and P2 now read 0 +/- 0.2. Repeat Tare Offset and Pressure Adjust until P1 and P2 reads displays 5 +/- 0.5 with 5 PSI applied and are 0 +/-0.5 with hand bulb open (0 pressure applied).

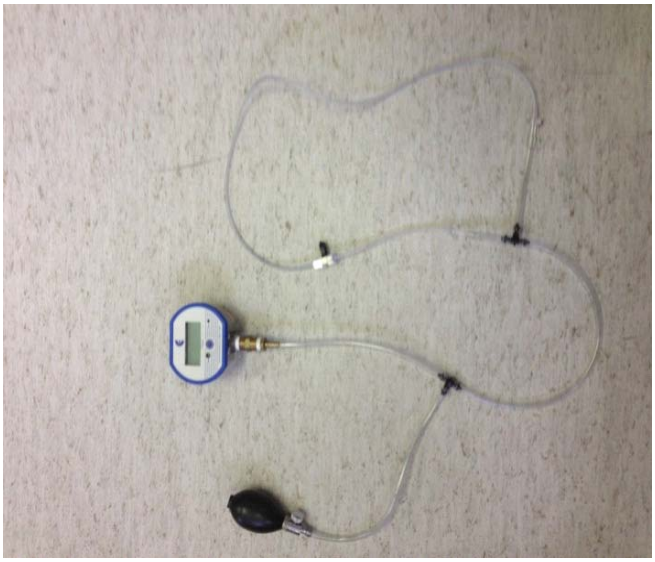
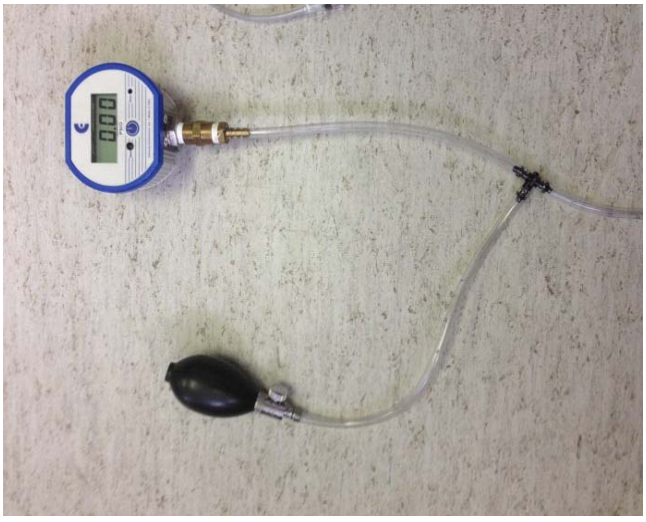
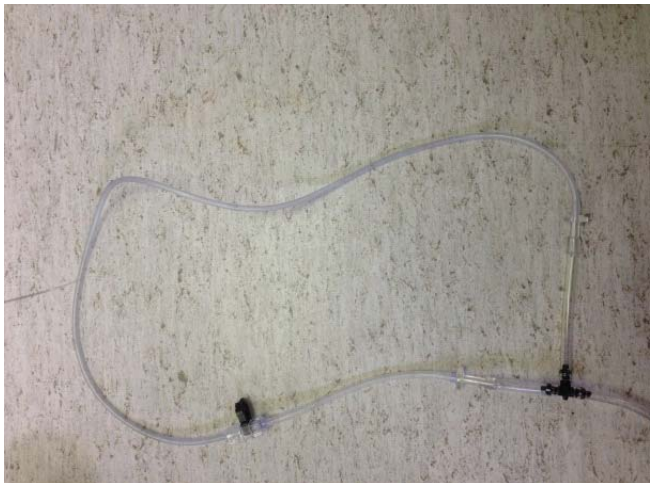


Figure 3-1.

Pressure test set made using a portion of the IVP105



0 to 15 PSI pressure guage with hand bulb pump & T fitting



IV1056 IV Set cut at top & bottom then connected to T fitting for connection to above.

3.2.4.3 Battery Verification

Insure battery is easly removed and does not show signs of swelling. (See Section 3.2.7.4 for swelled battery removal)

Press the F2 key And verify the following Battery Status, with charger cable connected. Note : Pryor to test connect charger cable to pump and allow battery to charge to at least 50%.

State of Charge (%) xxx [50 to 100]

Term. Voltage (V) xx.xxx [15 to 16.9]

Cell 1x.xxx [3.8 to 4.25]

Cell 2x.xxx [3.8 to 4.25]

Cell 3x.xxx [3.8 to 4.25]

Cell 4x.xxx [3.8 to 4.25]

(Note: All cells should be within .2 of each other)

Current (ma) xxx [+ 20 or greater]

Cycle count x [one or more]

S/N [Verify serial number matches 1133 Battery Pack serial Label installed in the pump]

Disconnect 1122 Charger Cable and verify battery current (ma) is approximately -240.

If battery shows signs of swelling or cells are not within 200 mv of each other the battery should be replaced.

Press Cancel key to return To Service Mode A.

3.2.4.4 Bubble Detect Verification:

With no IV Test Set installed verify Bubble detect indicated by Upper case "B" in the lower center of the display

3.2.4.5 Verify No Bubble Detect:

Load a IVP1056 set filled with fluid and verify no Bubble detect s indicated by Lower case "b" in the lower center of the display with the IV Test Set installed.

Power Off (O) key approximately 2 +/- 0.75 second and Power Off the pump.

3.2.4.6 Real Tim Clock Set & Verification

Set Time & Date; Press the (F3) soft key then the (F1) soft key to select the SET CLOCK Menu with Hour highlighted. Use the Up and Down arrows to adjust and ENTER key to set. Set the Clock to the current Date & Time. Navigate directly through the Time Menu with the (F2) soft key and directly through the Date Menu with the (F3) soft key. Press Menu key to enter Time and Date. Press Menu Key to enter Time and Date changes or Cancel key to exit without changing settings.

Press Power Off (0) Key

NOTE: To save the new time or date, the "MENU" key must be pressed prior to the "CANCEL" key when exiting this screen.

3.2.4.7 Flow preventer Switch Verification

For 3860 and 3860+ pumps, open Channel A door, press black pinch clamp in on IV Set Flow preventer assembly, verify Check Door A flashes at top of screen and pulsing alarm sounds within 2 seconds. Note: Flow switch must be On in service menu.

3.2.4.8 Flow Stop Pull Test

Load IVP1056 IV Set and Close Door. Open door verify black pinch clamp has been fully retracted (Flow stop is closed) and Flow preventer housing is retained in the gray/violet flow stop carrier (IVP1047/AS120).

NOTE: If pull test fails (black flow preventer not fully retracted) on a new Load IVP1056 IV set, the IVP1068 Door Clamp Clip is worn and should be replaced. Ref: AS112A drawing in Section 5, Assemblies and Drawings.

Power Pump Off.

3.2.4.9 Green Run and Red Alarm LED Verification:

Load a fluid filled set into the pump and close the door. Press Power On (I) key, select New Patient and verify normal Pump display. With the Rate 1.0 highlighted, press Enter again to Select a VTBI of .1. Verify Pump Displays "Unload Set", open the door,remove Fluid filled tubing from Bubble detector at bottom of Pump. Verify Display message changes to "Close Door". Close Door and verify "Close Door Message is removed from top of screen and "Push Start A" is flashing at bottom of screen. Press the start/stop key. Verify Green (run LED) begins flashing. Open the Door and verify Red alarm Led flashes and Speaker alarm sound. Press Alarm Cancel.

3.2.4.10 Sound Adjustment Verification:

Press the Menu Key then press (F3) to select Alarm Volume menu item. With the Up & Down arrow keys verify the alarm volume can be raised and lowered and saved to the appropriate setting.

3.2.4.11 3860 Remote Radio Verification

Connect 106 db attenuator cable from Pump Antenna Connector to Test Remote Antenna Connector or install Antennas on both both Pump and Remote .

3.2.4.11.1 Press Power (I) on Pump. If New Patient and Same Patient are displayed, press the (F1) soft key to select New Patient to bring up the normal Channel A display. From the normal Channel A display, press MENU key, press (F6) soft key to select Next Menu, press (F5) soft key to select Set Comm. Channel, then press (F1) soft key to select Channel 1.

3.2.4.11.2 Press power (I) on test Remote. If "No Communications" displayed, press MENU key, press (F6) soft key to select Next Menu, press (F5) soft key to select Set Comm. Channel, then press (F1) soft key to select Channel 1 and press Enter.

3.2.4.11.3 Check communication control between Pump and Remote as follows:

3.2.4.11.3.1 On Remote, press (F1) soft key to highlight Rate, then press Up arrow to set rate to 100 mL/hr, and then ENTER. With VTBI highlighted press Up arrow and set VTBI to 200 mL. Load IV Set in Pump, verify Ready to Start is displayed on both Pump and Remote. Press Start Channel A Remote and verify green (run) LED is flashing on both Pump and Remote.

3.2.4.11.3.2 Occlude inlet of IV Set above Pump and verify Red Alarm LEDs are flashing and speaker Alarm sounds on both Pump and Remote. Press ALARM SILENCE key on remote, verify Alarm sound is silenced, and Alarm LEDs stop flashing on both Pump and Remote. Press Start Channel A Remote and verify green (run) LED is flashing on both Pump and Remote.

3.2.4.11.3.3 On Remote, press MENU key. Press (F1) soft key to select Dose Rate Calculation and verify Dose Rate A screen is displayed on both Pump and Remote. Press CANCEL key.

3.2.4.11.3.4 On Remote press the (F3) soft key to select Alarm Volume. Verify Alarm Volume screen is displayed on Remote and "Adjusting the Remotes' Alarm Volume" is displayed on the Pump. Verify pressing the Remotes' Down arrow key lowers the volume and causes the displayed bar to move to the left of the screen. Pressing Remotes' Up arrow key increases the volume and causes the displayed bar to move to the right of the screen. Return displayed bar to the center of screen, then press the ENTER key.

3.2.4.11.3.5 On Pump, press the (F3) soft key to select Alarm Volume. Verify Alarm Volume screen is displayed on Pump and Adjusting the Pumps' Alarm Volume is displayed on the Remote. Pressing Pumps' Up arrow key increases the volume and causes the displayed bar to move to the right of the screen. Verify pressing the Pumps' Down arrow key lowers the volume and causes the displayed bar to move to the left of the screen and at lowest alarm volume is still audible. Return displayed bar to the center of screen, then press the ENTER key.

3.2.4.11.3.6 Press (F6) Next Menu then press the (F2) soft key to select Occlusion Limit. Verify Occlusion Limit screen is displayed. Verify that pressing the Down arrow key decrements 0.1 psi with each press to 1 psi. Verify pressing the Up arrow key increments 0.1 psi with each press to 10 psi and press Enter key.

3.2.4.11.3.7 Press the (F6) soft key to select Next Menu. Press the (F1) soft key to select KVO rate. Verify pressing the Up and Down arrow keys selects from 1 to 5 mL/hr for the 3850 and from 0 to 5mL/hr for the 3860. Return setting to 1 mL/hr., then press the ENTER key.

3.2.4.11.4 3861 SideCar Verification:

Install Test 3861 Side Car on Pump if SideCar is to be used with pump. Press Pump (I) key and verify Pump Power is On. Resume Therapy screen appears, press Same Patient. Select Channel B and verify the following:

3.2.4.11.5 Press Channel B (F6) soft key, press (F1) soft key, set Rate of 83.2 and press ENTER. Press Up arrow and set VTBI to 999 on start Channel B. Unload set if necessary and ensure "Ready to Run B". Press START/STOP Channel B, and verify Green (run LED) begins flashing on SideCar.

3.2.4.11.6 Occlude outlet line below SideCar Pump and verify Red alarm LED on SideCar flashes and Speaker Alarm sounds and message "PT Occluded B" flashes on the screen.

3.2.4.11.7 Press (0) Power Off key for 2 seconds to Power off Pump. Press and hold the CANCEL key and press the Power On (I) key to enter Service Mode. Press START/STOP Channel B key, verify Service Mode B is now displayed. With IV Set installed, verify small "b" at bottom of screen. Remove IV Set and verify large "B" at bottom of screen.

Press (0) Power Off key for 2 seconds to Power Off Pump. Remove Battery, then remove 3861 Test SideCar.

3.2.5 10 Key Pad Verification (3860 only)

Press the Power On (I) key, Select New Patient (F1) and verify normal Primary A display.

3.2.5.1 Using 10 key pad with Rate highlighted enter 123, verify tone with each key press and then press enter verifying 123 entered in rate.

3.2.5.2 Using 10 key pad with VTBI highlighted enter 456, verify tone with each key press and then press enter verifying 456 entered in VTBI.

3.2.5.3 Using 10 key pad with Rate highlighted enter 789, verify tone with each key press and then press enter verifying 789 entered in rate.

3.2.5.4 Using 10 key pad with VTBI highlighted enter 900, verify tone with each key press and then, press C and verify VTBI displays 0. Enter 999 Using 10 key pad, then press Enter.

3.2.5.5 Using 10 key pad with Rate highlighted enter 83.2, verify tone with each key press and then press enter verifying 83.2 entered in rate. Press Start A.

3.2.6 Pump Flow Test.

Pump flow test can be preformed using a Infusion Pump Analyzer or a graduated beaker. Place Pump on IV Pole with IVP1056 infusion set connected to 1000 ML distilled water bag. Place output of IVP1056 infusion set into 100 ML empty graduated beaker or connect to Infusion Pump Analyzer.

Load Primed infusion set (IVP1056) into Pump. Run the pump at a high rate (1400 or 999 ML) insure there are no air bubbles traped in the Y sites of the Infusion.

IF using graduated beaker be sure to empty after each flow test.

3.2.6.1 Set the Pump Rate to 1400 mL/hr., & VTBI >46.6 mL. Press Start/Stop A on the Pump. Verify the pump is running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door, and rate is set to 1400 mL/hr. Press Go in the Infusion Analyser or monitor graduated beaker. The Pump will run for approximately 2 min then go to KVO. Press Start/Stop A on the Pump and verify average flow rate on infusion analyzer is 1400 ml +/- 5% or graduated beaker contains 46.6 ml +/- 5%. (44.27 - 48.93)

3.2.6.2 Set the Pump Rate to 999 mL/hr., & VTBI >33.3 mL. Press Start/Stop A on the Pump. Verify the pump is running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door, and rate is set to 999 mL/hr. Press Go in the Infusion Analyser or monitor graduated beaker. The Pump will run for approximately 2 min then go to KVO. Press Start/Stop A on the Pump and verify average flow rate on infusion analyzer is 999 ml +/- 5% or graduated beaker contains 33.3 ml +/- 5%. (31.634 - 34.965)

3.2.6.3 Set the Pump Rate to 500 mL/hr., & VTBI >16.6 mL. Press Start/Stop A on the Pump. Verify the pump is running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door, and rate is set to 500 mL/hr. Press Go in the Infusion Analyser or monitor graduated beaker. The Pump will run for approximately 2 min then go to KVO. Press Start/Stop A on the Pump and verify average flow rate on infusion analyzer is 500 ml +/- 5% or graduated beaker contains 16.6 ml +/- 5%. (15.77 - 17.43)

3.2.6.4 Set the Pump Rate to 125 mL/hr., & VTBI >10.4 mL. Press Start/Stop A on the Pump. Verify the pump is running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door, and rate is set to 125 mL/hr. Press Go in the Infusion Analyser or monitor graduated beaker. The Pump will run for approximately 5 min then go to KVO. Press Start/Stop A on the Pump and verify average flow rate on infusion analyzer is 125 ml +/- 5% or graduated beaker contains 10.4 ml +/- 5%. (9.88 - 10.92)

3.2.6.5 Set the Pump Rate to 25 mL/hr., & VTBI >4.2 mL. Press Start/Stop A on the Pump. Verify the pump is running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door, and rate is set to 25 mL/hr. Press Go in the Infusion Analyser or monitor graduated beaker. The Pump will run for approximately 5 min then go to KVO. Press Start/Stop A on the Pump

and verify average flow rate on infusion analyzer is 25 ml +/- 5% or graduated beaker contains 4.2 ml +/- 5%. (3.99 - 4.41)

3.2.7 SpO2 Verification

3.2.7.1 Connect 1170 test F.O. probe to pump. Press Cancel to return to Resume Therapy Screen, verify SpO2 is displayed in lower portion of screen on both Pump and Remote.

3.2.7.2 Connect 1170 test F.O. Probe to Pronk Technologies OxSim, insure IR and Red LEDs are on, and press mode switch to select 98% / 80bpm. Verify Pump displays SpO2 of 98% +/- 1 & 80 +/-1 BPM and PI: 4.0 +/- .5%.

3.2.7.3 Press Mode and select 99% Low Perf. Verify Pump and Remote displays SpO2 of 99% +/- 1, & 80 +/-1 BPM, and PI: 0.3 +/- .2%.

3.2.7.4 Select New Patient or verify normal Pump display with the Rate 1.0 highlighted. With a rate of 83.2 and VTBI of 999, open Door and insert IV Set filled with water and close Door. Press the START/ STOP key and verify Green (run LED) begins flashing and SpO2 is displayed in the lower portion of the screen on both Pump and Remote.

3.2.7.5 Press Mode and select 98%, 140 bpm. Verify Pump and Remote displays SpO2 of 98% +/- 1 & 140 +/-1 BPM and PI: 3.0 +/- .5%.

3.2.7.6 On Pump, press Menu, Next Menu (F6), Spo2 Menu (F4), and HR Hi Limit: (F2). Verify 200 bpm highlighted. With Down Arrow select 130 bpm and press Enter. On both the Pump and Remote, verify "High HR" displayed alternately with battery icon at top of screen, Alarm sound and Alarm LED. Reset HR Hi Limit to 200 bpm. Press ALARM SILENCE and verify "HIGH HR" is not displayed at the top of the screen.

3.2.7.7 Press Next Menu (F6) and select SpO2 menu (F4) and verify SpO2 Low Lim: 85% is highlighted. With Up Arrow select 90% and press Enter twice. With OxSim Mode switch select 85% 80 bpm. Verify Pump and Remote displays SpO2 of 85% +/- 1 & 80 +/-1 BPM, Low SpO2 displayed alternately with battery icon at top of screen, Alarm sound and alarm LED

3.2.7.8 Remove 1170 test F.O. Probe from OxSim and verify Probe Off, Alarm sound and Alarm LED flashing on both Pump and Remote.

3.2.7.9 Disconnect 1170 test probe from Pump and verify No Probe is displayed alternately with battery icon at top of screen, Alarm sound and Alarm LED. Press Alarm Silence and verify Alarm reset and SpO2 removed from screen on both Pump and Remote.

3.2.8 3861 PM Service Mode Verification

Reference the Section 2 Service Mode description. Service Mode is accessed by pressing the overlay KeyPad On (I) button and the holding the overlay KeyPad Cancel key depressed until the service Mode is displayed. Note, the following procedure is the same for both 3861Pump. Press B Start/Stop key to access Service Mode B.

3.2.8.1 Motor Speed Verification

Select MANUAL PUMP RUN, press and hold ENTER on Keypad (100% duty cycle). Verify speed to approximately 135 +/-30 RPM.

3.2.8.1.1 3861 Pressure Verification:

See Figure 1:Pressure test set made using a portion of the IVP1056 in section 3.2.4.

3.2.8.1.2 Tare Offset Verification:

Connect Pressure Gauge with Hand Bulb to a circular IV Test Set (no fluid) and with Hand Bulb open (0 PSI) See photo below. Open Door, Load IV Test Set, Close the Door and verify pump moves to index, press the F1 key, then press the F4 key (Tare Offset). Press the Cancel key to return to the Service Mode display and verify P3 and P4 are 0 +/- 0.5.

3.2.8.1.3 Pressure Verification:

Close Pressure Gauge Hand Bulb and apply 5.0 PSI per Pressure Gauge. Verify P3 and P4 displays 5 +/- 0.5

3.2.8.1.4 Pressure Adjustment:

If P3 and P4 did not display 5 +/- 0.5, ensure pressure gauge remains at 5.0, press the F1 Key (top left white key) to enter the Calibrate Pump screen, then press the F5 key (Span Cal). Press the Cancel key to return to the Service Mode display and verify P3 and P4 are now 5 +/- 0.5

3.2.8.1.5 Zero Verification after Adjustment:

Open pressure gauge hand bulb and verify P3 and P4 now read 0 +/- 0.2. Repeat Tare Offset and Pressure Adjust until P3 and P4 reads displays 5 +/- 0.5 with 5 PSI applied and are 0 +/-0.5 with hand bulb open (0 pressure applied).

3.2.8.1.6 Bubble Detect Verification:

With no IV Test Set installed verify Bubble detect indicated by Upper case "B" in the lower center of the display.

3.2.8.1.7 Verify No Bubble Detect:

Load a IVP1056 set filled with fluid and verify no Bubble detect s indicated by Lower case "b" in the lower center of the display with the IV Test Set installed. Power Off (O) key approximately 2 +/- 0.75 second and Power Off the pump

3.2.8.1.8 Flow preventer Switch Verification:

Press Power On (I) key, select New Patient and verify normal Pump display.Select channel B with

the F6 Key. Open Channel B door, press black pinch clamp in on IV Set Flow preventer assembly, verify Check Door B flashes at top of screen and pulsing alarm sounds within 2 seconds. Note: Flow switch must be On in service menu.

3.2.8.1.9 Flow Stop Pull Test:

Open door verify black pinch clamp has been fully retracted (Flow stop is closed) and Flow preventer housing is retained in the gray/violet flow stop carrier (IVP1047/AS120).
Note: If pull test fails (black flow preventer not fully retracted) on a new 1000 series IV set, the IVP1068 Door Clamp Clip is worn and should be replaced.
Ref: AS112A drawing in Section 5, Assemblies and Drawings.

3.2.8.1.10 Green Run and Red Alarm LED Verification:

With a fluid filled set into the 3861 pump and close the door and "Push Start B" is flashing at bottom of screen. Press the B start/stop key. Verify Green (run LED) begins flashing. Open the Door and verify Red alarm Led flashes and Speaker alarm sound. Press Alarm Cancel.

3.2.9 3861 Pump Flow Test:

3.2.9.1 Pump flow test can be preformed using a Infusion Pump Analyzer or a graduated beaker. Place Pump on IV Pole with IVP1056 infusion set connected to 1000 ML distilled water bag. Place output of IVP1056 infusion set into 100 ML empty graduated beaker or connect to Infusion Pump Analyzer**.**

Load Primed infusion set (IVP1056) into Pump. Run the pump at a high rate (1400 or 999 ML) insure there are no air bubbles traped in the Y sites of the Infusion.

3.2.9.2 If using a graduated beaker, be sure to empty after each flow test.If pump being tested is 3861 run following test, if pump being tested is 3851 N/A this test step.

3.2.9.3 Set the Pump Rate to 1400 mL/hr., & VTBI >46.6 mL. Press Start/Stop B on the Pump. Verify the pump is running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door, and rate is set to 1400 mL/hr. Press Go in the Infusion Analyser or monitor graduated beaker. The Pump will run for approximately 2 min then go to KVO. Press Start/Stop B on the Pump and verify average flowrate on infusion analyzer is 1400 ml +/- 5% or graduated beaker contains 46.6 ml +/- 5%. (44.27 - 48.93)

3.2.9.4 Set the Pump Rate to 999 mL/hr., & VTBI >33.3 mL. Press Start/Stop B on the Pump. Verify the pump is running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door, and rate is set to 999 mL/hr. Press Go in the Infusion Analyser or monitor graduated beaker. The Pump will run for approximately 2 min then go to KVO. Press Start/Stop B on the Pump

and verify average flow rate on infusion analyzer is 999 ml +/- 5% or graduated beaker contains 33.3 ml +/- 5%. (31.634 - 34.965)

3.2.9.5 Set the Pump Rate to 500 mL/hr., & VTBI >16.6 mL. Press Start/Stop B on the Pump. Verify the pump is running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door, and rate is set to 500 mL/hr. Press Go in the Infusion Analyser or monitor graduated beaker. The Pump will run for approximately 2 min then go to KVO. Press Start/Stop B on the Pump and verify average flow rate on infusion analyzer is 500 ml +/- 5% or graduated beaker contains 16.6 ml +/- 5%. (15.77 - 17.43)

3.2.9.6 Set the Pump Rate to 125 mL/hr., & VTBI >10.4 mL. Press Start/Stop B on the Pump. Verify the pump is running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door, and rate is set to 125 mL/hr. Press Go in the Infusion Analyser or monitor graduated beaker. The Pump will run for approximately 5 min then go to KVO. Press Start/Stop B on the Pump and verify average flow rate on infusion analyzer is 125 ml +/- 5% or graduated beaker contains 10.4 ml +/- 5%. (9.88 - 10.92)

3.2.9.7 Set the Pump Rate to 25 mL/hr., & VTBI >4.2 mL. Press Start/Stop B on the Pump. Verify the pump is running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door, and rate is set to 25 mL/hr. Press Go in the Infusion Analyser or monitor graduated beaker. The Pump will run for approximately 5 min then go to KVO. Press Start/Stop A on the Pump and verify average flow rate on infusion analyzer is 25 ml +/- 5% or graduated beaker contains 4.2 ml +/- 5%. (3.99 - 4.41)

3.2.10 3865 PM Verification

Connect 106db attenuator cable from Remote Antenna Connector to Test Pump Antenna Connector or install Antennas on both both Remote and Pump. Note 3860 Pump must be used to test 3865 Remote and 3850 Pump must be used to test 3855 Remote.

3.2.10.1 Press Power (I) on Pump. If New Patient and Same Patient are displayed, press the (F1) soft key to select New Patient to bring up the normal Channel A display. From the normal Channel A display, press MENU key, press (F6) soft key to select Next Menu, press (F5) soft key to select Set Comm. Channel, then press (F1) soft key to select Channel 1.

3.2.10.2 Press power (I) on 3865 Remote. If "No Communications" displayed, press MENU key, press (F6) soft key to select Next Menu, press (F5) soft key to select Set Comm. Channel, then press (F1) soft key to select Channel 1 and press Enter.

3.2.10.3 Check communication control between Pump and Remote as follows:

3.2.10.3.1 On 3865 Remote, press (F1) soft key to highlight Rate, then press Up arrow to set rate to 100 mL/hr, and then ENTER. With VTBI highlighted press Up arrow and set VTBI to 200 mL. Load IV Set in Pump,

verify Ready to Start is displayed on both Pump and Remote. Press Start Channel A Remote and verify green (run) LED flashes on both Pump and Remote.

3.2.10.3.2 Occlude inlet of IV Set above Pump and verify Red Alarm LEDs are flashing and speaker Alarm sounds on both Pump and Remote. Press ALARM SILENCE key on remote, verify Alarm sound is silenced, and Alarm LEDs stop flashing on both Pump and Remote. Press Start Channel A Remote and verify green (run) LED is flashing on both Pump and Remote.

3.2.10.3.3 On 3865 Remote, press MENU key. Press (F1) soft key to select Dose Rate Calculation and verify Dose Rate A screen is displayed on both Pump and Remote. Press CANCEL key.

3.2.10.3.4 On 3865 Remote press the (F3) soft key to select Alarm Volume. Verify Alarm Volume screen is displayed on Remote and "Adjusting the Remotes' Alarm Volume" is displayed on the Pump. Verify pressing the Remotes' Down arrow key lowers the volume and causes the displayed bar to move to the left of the screen. Pressing Remotes' Up arrow key increases the volume and causes the displayed bar to move to the right of the screen. Return displayed bar to the center of screen, then press the ENTER key.

3.2.10.3.5 On Pump, press the (F3) soft key to select Alarm Volume. Verify Alarm Volume screen is displayed on Pump and Adjusting the Pumps' Alarm Volume is displayed on the Remote. Pressing Pumps' Up arrow key increases the volume and causes the displayed bar to move to the right of the screen. Verify pressing the Pumps' Down arrow key lowers the volume and causes the displayed bar to move to the left of the screen and at lowest alarm volume is still audible. Return displayed bar to the center of screen, then press the ENTER key.

3.2.10.3.6 On 3865 Remote press (F6) Next Menu then press the (F2) soft key to select Occlusion Limit. Verify Occlusion Limit screen is displayed. Verify that pressing the Down arrow key decrements 0.1 psi with each press to 1 psi. Verify pressing the Up arrow key increments 0.1 psi with each press to 10 psi and press Enter key.

3.2.10.3.7 On 3865 Remote the (F6) soft key to select Next Menu. Press the (F1) soft key to select KVO rate. Verify pressing the Up and Down arrow keys selects from 1 to 5 mL/hr for the 3855 and from 0 to 5mL/hr for the 3865. Return setting to 1 mL/hr., then press the ENTER key.

3.2.10.4 10 Key Pad Verification (3865 Remote) only.

3.2.10.4.1 On the 3865 Remote using 10 key pad with Rate highlighted enter 123, verify tone with each key press and then press enter verifying 123 entered in rate.

3.2.10.4.2 On the 3865 Remote using 10 key pad with VTBI highlighted enter 456, verify tone with each key press and then press enter verifying 456 entered in VTBI.

3.2.10.4.3 On the 3865 Remote using 10 key pad with Rate highlighted enter 789, verify tone with each key press and then press enter verifying 789 entered in rate.

3.2.10.4.4 On the 3865 Remote using 10 key pad with VTBI highlighted enter 900, verify tone with each key press and then, press C and verify VTBI displays 0. Enter 999 Using 10 key pad, then press Enter.

3.2.10.4.5 On the 3865 Remote using 10 key pad with Rate highlighted enter 83.2, verify tone with each key press and then press enter verifying 83.2 entered in rate. Press Start A.

3.2.11 Battery Pack Maintenance

Over discharge, over charge and over current (short-circuit) are all conditions detected by the internal "smart power gauge" of the battery. These conditions all result in the battery shutdown (battery will not deliver power) until placed into charge. Over discharge can cause cells to outgas during subsequent charge cycles. Severe outgassing can result in the battery pack swelling. Replace any battery pack with visible signs of deformation or swelling.

It is important to understand the basic chemistry of lithium polymer batteries. These batteries are a limited-life technology. The useful life of the battery pack is affected by chemical processes which start the day the each of the cells inside the battery pack are made. The life can be further shortened by the way the cells are used and stored. These cells will die faster if they are not held at some small level of charge (50%) during non-use periods. If they are stored with any cell below 3.0V, a higher percentage of the cells will start to outgas and swell. If they go to very low voltages, they may not charge well and make even more gas.

The 1138 Operator's Manual includes many cautions and suggestions for caring for the battery. But lithium polymer batteries are sensitive use and storage conditions, and inherently have a limited useful life. From the chemical standpoint and normal distribution of failure, we expect less than 5% should need replacement in less than 6 months. If you see more than 10% of your batteries need replacement within 6 months of installation, we must look closely at the use and storage conditions.

3.2.11.1 1133 Battery Pack Maintenance Checkout Procedure

The 1133 Battery Pack should be inspected anytime the pack is removed, or at least every 90 days for the following:

3.2.11.1.1 Battery Pack communicates with the Pump. This indicated by the Battery Icon being shown on the display of the Pump or Remote Display. Refer to Section 1.3.1 of this manual for Battery Icon description.

3.2.11.1.2 The Battery Pack holds sufficient operating charge capacity. This is indicated by allowing the Pump to operate on battery power for the recommended minimum time.

3.2.11.1.3 Battery Pack "Gas Gauge" indicator functions. These functions can be confirmed by removing the battery and pressing the test button on the battery a fully charged battery will have 5 green bars as shown below test button. The battery Gas Gauge is also displayed in the upper left corner of the display screen.

3.2.11.1.4 Physical Inspection of the Battery Pack case. Remove the Battery Pack from the Pump or Remote Display, and inspect for physical damage or signs of mechanical shock, cracked casing or swollen case.

3.2.11.1.5 Physical Inspection of the Battery Pack cell(s). Remove the Battery Pack from the Pump or Remote Display, and confirm that cells inside the Battery Pack are not swelling excessively, as noted by viewing internal cells from the edge of the Battery Pack case. Swollen cells that are greater than 8 mm thick, or cause the Battery Pack's plastic case to bulge indicate a failing battery pack.

3.2.11.1.6 Any failure of any of the above inspection criteria will require discontinuance of use and replacement of the 1133 Battery Pack.

3.2.11.2 Battery Pack Replacement

If the Battery Pack does not operate for the specified time after a full nine (9) hour charge cycle, replacement of the Battery Pack is recommended.

CAUTION

If placed into storage, to maintain battery life, assure that the battery pack remains charged above 25% (one battery segment is visible) as indicated by the “gas gauge” LED display.

3.2.11.3 Battery Pack Related Precautions

The 1133 Battery Pack contains several lithium-polymer cells and an integral safety circuit. As these cells age, they can expand due to internal gas release, which is anticipated for this type of cell. However, if excessive expansion occurs, this can result in the battery case expanding (swelling), and possibly cause failure of the battery case, cells, or safety circuit. If this is observed, remove the Battery Pack from use and replace it as soon as possible.

The 1133 Battery Pack contains protective circuitry to prevent catastrophic battery failure. If the Battery pack is damaged, this protective circuitry may not prevent battery failure. Remove the Battery Pack from use if the Pack becomes damaged, or the potential for Battery Pack damage is suspected.

Do not use a damaged or swollen 1133 Battery Pack.

Avoid damage to the 1133 Battery Pack by impact, dropping, overheating, or mechanical abuse. Never compress, drop, shock, or strike the 1133 Battery Pack. Never use objects that could puncture the internal battery cells. Any of these actions can cause the battery cells to heat, smoke, or cause catastrophic battery failure, which could result in fire. Do not attempt to disassemble the 1133 Battery Pack. Damage caused by disassembly or tool use can result in catastrophic battery failure, which could result in fire.

If the 1133 Battery Pack case begins to expand and/or swell, discontinue battery charging and use immediately, and replace the Battery Pack. Continued charging will cause further Battery Pack case expansion, with possible battery case fracture, and potential electrolyte leakage.

If the 1133 Battery Pack becomes damaged, avoid contact with the battery cell electrolyte. If the electrolyte contacts the skin or eyes, seek medical attention immediately.

If the 1133 Battery Pack shows sign of the battery case expanding (swelling), remove the Battery Pack from use and replace it as soon as possible. In extreme conditions, this swelling can cause the 1133 Battery Pack to become jammed or stuck within the 3860+ Pump or 3865 Remote Display, and/or cause the Battery Pack plastic case to burst open. If this occurs, do not use tools that could cause damage to the internal battery cells (see Section 3.2.7.4 below for removal instructions).

3.2.12 Removing a swelled Battery Pack (Figure 3-2)

In the event a Battery Pack swells and becomes stuck in the chassis of the 3860+ or 3865, removal can become difficult. To assure that removing the battery will not cause any damage to the Pump or Remote, the following steps should be taken:

3.2.12.1 Turn Power "OFF" on the Pump or Remote before attempting removal.

3.2.12.2 Place either Pump or Remote, face down, on a solid surface with some kind of soft protective covering (to prevent damage to face of Pump or Remote).

3.2.12.3 Using a small "dull" flat blade screwdriver in your right hand, work the area between the top of the battery and the back case as shown (see Figure 3-3) until battery begins to release from chassis (with your left hand you will need to release the battery latch at the same time).

3.2.12.4 Once a small gap is established and the battery has moved enough to release the latch and a larger gap battery and the back case, using a larger "dull" blabe screwdriver begin softly tapping the end of the screwdriver with a mallet, moving the screwdriver in a downward angular motion being sure to keep the screwdriver blade on the reinforced ribbed portion of the battery, forcing the battery out of the Pump or Remote. Move to each side of the battery to insure even rearward force is applied.

3.2.12.5 If battery is so swelled that using this method does not prove successful, or if the batterys plastic case begins to crack at the point of contact, or the screw driver penetrates the plastic, please discontinue attempting removal and contact Iradimed Corporation Technical Service immediately at 1-407-677-8022.

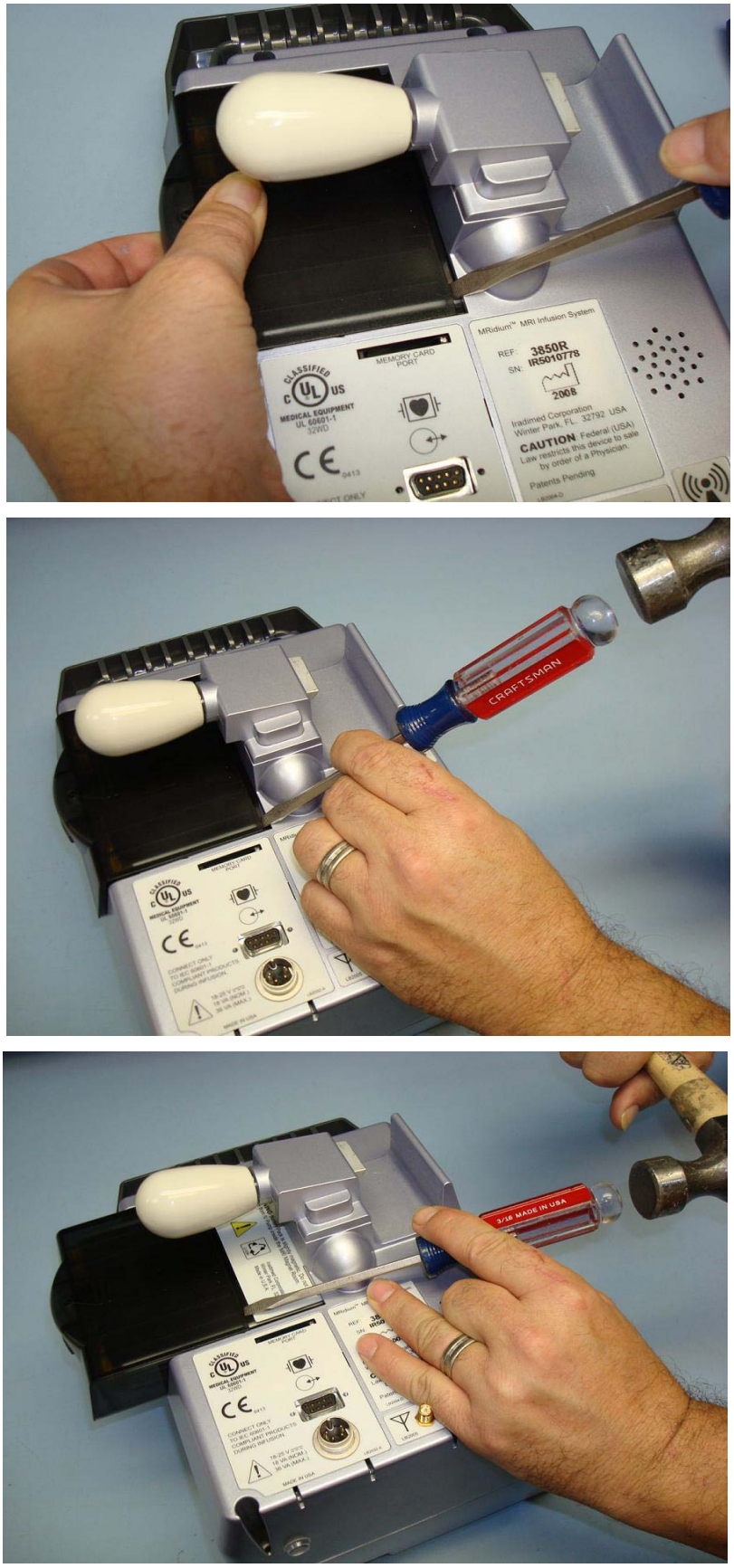

MRidium™ MRI Infusion System
REF 3850R
SN: IRS010778
2008
Iradimed Corporation
Winter Park, FL 32792 USA
CAUTION Federal (USA) Law restricts this device to sale by order of a Physician.
Patents Pending
MEMORY CARD PORT
CLASSIFIED
MEDICAL EQUIPMENT
UL 60601-1
32WD
CRAFTSMAN
3/16 MADE IN USA

Figure 3-2.

3.3 Software Update

IMPORTANT: Prior to loading software insure the AC power cord to the power/ charger is plugged into line power and the DC charger cable is plugged into the pump or the battery has sufficient charge to complete software update (which takes less than 3 minutes). Never turn the pump off while updating software as the current program will be lost. Failure to follow these instructions will disable your pump and require it to be returned to Iradimed Corporation for repair.

3.3.1 To determine the current software version of the MRidium Infu sion pump or Remote perform the following:

With the pump off, turn the pump on, as it goes through its self-check, the words "Powering on: X.X.XXXX" should appear momentarily before the main programming screen or Resume Therapy screen appears. The software version is displayed in X.X.XXXX format (e.g. Powering on: 3.5.1).

3.3.2 To update the current software version of the MRidium Infusion pump or Remote perform the following:

1. With the pump turned off, place the SD card into the slot located below the battery compartment on the back above the rear connector ports with card notch to right as shown below (Figure 3-3).

IMPORTANT: If you or your clinical users have stored any internal user preset values for the 5 standard drugs in the Dose Rate Calculator (refer to Section 1.6 for this procedure), make sure these settings have been recorded before the software has been updated. Any custom user presets will be reset to factory default values after any software update is performed, and will need to re-stored before use (refer to Section 1.6).

Figure 3-3.

2. Turn the pump on. The software will automatically begin to load. After a few minutes, the update will be completed, and the screen will return to the normal new program screen.

3. Turn the pump off and then remove the card.

IMPORTANT: Be sure to remove the card after update as the software is loaded each time the pump is turned on.

IMPORTANT: If using the 1145 DERS Library Card feature, re-install the 1145 DERS SD Memory card and its retaining clip before use (refer to Section 3.4).

4. To verify the software was updated properly, turn the pump back on, as it goes through its self check, the words "Powering on: X.X.XXXX" should appear momentarily before the main programming screen or Resume Therapy screen appears. Verify X.X.XXXX is the same as the revision of the AM04 update card. Also see Section 3.8.4 for the 3865 Software Update Verification.

NOTE: As many software updates may provide new or enhanced features the operators MUST be made aware that software has been updated. Always provide the operators such warning and copy of new operations manual/ instructions.

WARNING: When updating pumps utilizing the 1145 DERS drug library or where users have programmed "Custom Drugs", proper library operation should be re-validated. If you or your clinical users have programmed any custom settings for the 5 standard drugs in the Dose Rate Calculator (refer to Section 1.6 for this procedure), you will need to re-program these custom settings (in the Service Mode) after the software has been updated. Any custom settings will be reset to factory default values after any software update is performed.

3.4 Dose Error Reduction System (DERS) Option Installation

Refer to Iradimed Corporation Document SD005-B for the installation of the 1145 DERS Software Upgrade. For a copy of this document contact customer service toll free at: 866-677-8022.

3.5 Systems Test

Perform the following tests for a complete verification of the systems of the mRidium IV pump family. If a major component is replaced, the test may be resumed at point of failure, unless previous test steps are related with the replaced component. IVPAB001, IVPAB002 in the 3860+ pump, IVPAB011 (3861 SideCar) and the AS100 pump assembly in both the 3860+ and 3861 are components that require the restart of a complete test. Note, the following procedure is the same for both 3860+ Pump (Service Mode A) and 3861 SideCar (Service Mode B). When testing the 3861 SideCar, always remove all power including 3860+ Pump battery when making connections for testing.

3.5.1 Reference Documents

Infutest 2000 Operation Manual

Sartorius Model GD603 or DG605 Scale Operation Manual

3860 Operation Manual REF 1138

3.5.2 Test Equipment Needed

(For complete detail system testing/calibration)

4.5 digit DMM (BK model 1670A) or equivalent.

Regulated DC Power Supply, 20+V/3A.

20+ MHZ Dual Channel Oscilloscope (Tectronix TDS210) or equivalent.

PC with serial port RS-232 capability.

Test Software provided on 1125 Service Manual CD.

Sartorius Model GD603 or GD605 Scale with RS-232 connection.

Infutest 2000 IV Pump Test set (or equivalent)

Iradimed 1000 Series IV Sets and IV pole.

IV Fluid Container (Distilled Water)

Closed Continuous Flow Circular/Looped Series 1000 IV Set.

Pressure gauge (0 to 10 psi) and pressure means (ie: hand bulb).

IVPAB009 PCBA & Test Adapter Cable Set.

SideCar Pump Test Adapter Cable Set.

106 db RF Attenuator Cable.

Battery Test Cable.

TF009 Battery Simulator Test Fixture

Pronk Technologies OxSim, OX-1 SpO2 Finger Simulator (3860+ only)
Pull force gauge or spring balance

3.5.3 Basic Tools

#1 Phillips Screw Driver

#2 Phillips Screw Driver

PH00 Phillips

9/64” Allen Driver or T Bar

3 mm Allen Driver or T Bar

3/16” Nut Driver

100 mL and/or 25 mL Graduated cylinder (Simple flow testing)

MRidium IV sets

3.6 MRidium MR IV Pump, main unit, Verification (3860+)

(Reference IVPAB001 assembly drawing in section 5.)

3.6.1 DC Input Verification

3.6.1.1 Connect DC Power Supply to POWER IN connector (+ to P6-2 or 3 & - to P6 1 or 4), ensure DC Power Supply is set to 0vdc.

3.6.1.2 Install Test Connector with 1.2K Ohm resistor at P8. With DMM, monitor supply power voltage (Raw Power) at P8-2. Use power supply (-) for GND.

3.6.1.3 Turn on DC power supply (0vdc) and slowly increase Power Supply voltage to 12vdc. Verify current draw from power supply < 0.01A and P8-2 voltage < 2.0vdc.

3.6.1.4 Increase Power Supply voltage to approximately 16.5vdc +/- 0.5vdc. Verify P8-2 turns on at 16.5vsc +/- 0.6vdc and Voltage matches the supply +/- 0.5vdc.

3.6.1.5 Remove test connector with 1.2K used in step 1.2. Increase Power Supply to 19vdc. Verify current draw from supply < 0.030A.

3.6.1.6 Press Power On (I) Key and from Normal Display adjust R103 (Display Contrast) on IVPAB002 for best viewing of display contrast.

3.6.1.7 Verify Power Off requires ≥ 2 second depression of the Power Off (O) key.

3.6.1.8 Press overlay KeyPad On (I) button. Verify and record thefollowing :

3.6.1.8.1 IVP-AB001 TP 1 is 11.75V +/- 0.5V

3.6.1.8.2 IVP-AB001 TP 2 is 5V +/- 75mV

3.6.1.8.3 IVP-AB001 TP 3 for 3.3V +/- 75mV

3.6.1.9 Press overlay KeyPad Off (0) button for 2 Seconds.

3.6.2 Battery Input Verification.

Apply DC Power Supply Voltage to AB001 P2 BATTERY connector (P2 pins 1&6 to gnd, P2 pins 2&5 to +). Set DC Power Supply to 12vdc into P2 BATTERY, verify pump will not power on.

3.6.2.1 Set DC Power Supply to 13.8vdc, verify pump will now power on and Off.

3.6.2.2 With Pump On, Reduce DC Power Supply voltage slowly until TP3 (3.3VDC) drops off and pump powers Off. Verify DC Power Supply is at 10VDC +/-0.5 VDC.

3.6.2.3 Set input DC Power Supply to 16 VDC. Turn Pump ON then OFF using power switch Keypad On (I) button. Verify “OFF” state and leakage current from DC Power Supply is <3mA.

3.6.2.4 Turn off DC Power Supply. Disconnect supply line from P2 BATTERY connector.

3.6.3 Battery Charge Verification & Adjustment

The following requires Iradimed TF009 Battery Simulator:

3.6.3.1 Connect Battery Simulator TF009 to P2 BATTERY connector and connect DC Power Supply to P6 POWER IN connector. Connect meter to measure Amps to Battery Simulator (This is the DC Power Supply current). Ensure TF009 Battery Simulator Load Knob is turned fully counter-clockwise. Set DC Power Supply to 19 VDC. Adjust Battery Simulator Load Knob clockwise until charge current flows. Verify Power LED is lit Green and changes to Yellow (or Amber) when charge current begins to flow.

3.6.3.2 Adjust Battery Simulator Load Knob fully CCW for maximum charge current. Verify current 1.4A +/- 0.2A and Power LED remains Yellow (or Amber).

3.6.3.3 Adjust Battery Simulator Load Knob CW for 0.50A +/-0.03A and adjust CHRG Pot R89 for 16.82V +/-0.01V at P2-2.

3.6.3.4 Disconnect Battery Simulator cable from P2 BATTERY connector.

3.6.3.5 Reconnect internal P2 BATTERY connector.

3.6.4 Pump Motor Speed Adjustment

Reference the Section 2 Service Mode description. Put Pump into Service Mode by pressing Keypad On (I) button and holding the Keypad CANCEL key depressed until the Service Mode is displayed.

3.6.4.1 Set R41 (feedback) fully CW. R57 (frequency) fully CCW, R52 (speed) fully CCW. Scope Setup: Channel 1, Sweep Speed to 2ms, 100v/division. Channel 2, Sweep Speed to 2ms, 2v/division.

3.6.4.2 Select MANUAL PUMP RUN, press and hold ENTER on Keypad (100% duty cycle). Adjust R57 CW until speed begins to increase or speed reaches approximately 60-70 RPM. Ensure motor is running CCW (when viewed from the motor end).

3.6.4.3 Adjust R41 fully CCW and note speed is above 240 RPM. Then Reduce speed by turning R41 CW until speed reaches 130~150 RPM.

3.6.4.4 Connect Channel 1 (set to 100V/Div) to PJ5R Pin 1 on IVPAB001 board. Connect Channel 2 (set to 2V/Div) to Encoder output A (J1 pin 3 of the IVPAB043 or P1 pin 3 of the IVPAB003 Board) sync on Channel 2. Select index and press enter. Verify motor goes to index. Select Rate and set to 20, press Start/Stop A. Adjust R57 drive pulse Channel 1 to 4~8ms. Ensure that Channel 2 is measuring 2 pulses (tics). Monitor the lower left counter on the display (displays encoder position from 0 to 1000), verify at least three revolutions. Insure encoder position count rolls over at 1000 back to 1, count should not count more than 2 tics above 1000.

3.6.4.5 If counter is greater than 1002 before it rolls over to 0, read-just R57 (may require more than 8 ms). Press Start/Stop A Key.

3.6.4.6 Verify speed is still at 130~150 RPM, by selecting Manual Pump Run and press Enter.

3.6.4.7 Select MANUAL PUMP RUN with the arrow keys and depress and hold the ENTER Key. With Scope Amplitude to 100V / division and connect Channel 1 to PJ5R pins 1 and 5. Verify >300 P-P and > 100V RMS and frequency is 44.5 KHz +/-2.5 KHz.

3.6.5 Time and Date Verification

3.6.5.1 Set Time & Date; Press the (F3) soft key then the (F1) soft key to select the SET CLOCK Menu with Hour highlighted. Use the Up and Down arrows to adjust and ENTER key to set. Set the Clock to the current Date & Time. Navigate directly through the Time Menu with the (F2) soft key and directly through the Date Menu with the (F3) soft key. Press Menu key to enter Time and Date.

3.6.5.2 Press Power Off (0) Key for 2 seconds and verify Pump powers Off.

3.6.5.3 Return to SERVICE MODE by pressing Keypad On (I) button and holding the Keypad CANCEL key depressed until the SERVICE MODE is displayed. Verify Time and Date is saved correctly by pressing (F3) soft key and then the (F1) soft key. Press Cancel Key twice to return to Service Mode A.

3.6.6 3860+3860+ Pressure Verification

See Figure 1:Pressure test set made using a portion of the IVP1056 in section 3.2.4.

3.6.6.1 Tare Offset Verification :

Connect Pressure Gauge with Hand Bulb to a circular IV Test Set (no fluid) and with Hand Bulb open (0 PSI) See photo below. Open Door, Load IV Test Set, Close the Door and verify pump moves to index, press F1 key, then press F4 key (Tare Offset). Press the Cancel key to return to the Service Mode display and verify P1 and P2 are 0 +/-0.5.

3.6.6.2 Pressure Verification :

Close Pressure Gauge Hand Bulb and apply 5.0 PSI per Pressure Gauge. Verify P1 and P2 displays 5 +/- 0.5.

3.6.6.3 Pressure Adjustment:

If P1 and P2 did not display 5 +/- 0.5, ensure pressure gauge remains at 5.0, press the F1 Key (top left white key) to enter the Calibrate Pump screen, then press the F5 key (Span Cal). Press the Cancel key to return to the Service Mode display and verify P1 and P2 are now 5 +/- 0.5.

3.6.6.4 Zero Verification after Adjustment :

Open pressure gauge hand bulb and verify P1 and P2 now read 0 +/- 0.2. Repeat Tare Offset and Pressure Adjust until P1 and P2 reads displays 5 +/- 0.5 with 5 PSI applied and are 0 +/-0.5 with hand bulb open (0 pressure applied).

3.6.7 Battery Verification :

Insure battery is easly removed and does not show signs of swelling. (See Section 3.2.7.4 for swelled battery removal)

Press the F2 key And verify the following Battery Status, with charger cable connected. Note : Pryor to test connect charger cable to pump and allow battery to charge to at least 50%.

State of Charge (%) xxx [50 to 100]

Term. Voltage (V) xx.xxx [15 to 16.9]

Cell 1x.xxx [3.8 to 4.25]

Cell 2x.xxx [3.8 to 4.25]

Cell 3x.xxx [3.8 to 4.25]

Cell 4x.xxx [3.8 to 4.25]

(Note: All cells should be within .2 of each other)

Current (ma) xxx [+ 20 or greater]

cycle count x [one or more]

S/N [Verify serial number matches 1133 Battery Pack serial Label installed in the pump]
Disconnect 1122 Charger Cable and verify battery current (ma) is approximately -240.

If battery shows signs of swelling or cells are not within 200 mv of each other the battery should be replaced.

Press Cancel key to return To Service Mode A.

3.6.8 Bubble Detect Verification :

With no IV Test Set installed verify Bubble detect indicated by Upper case “B” in the lower center of the display.

3.6.9 Verify No Bubble Detect :

Load a IVP1056 set filled with fluid and verify no Bubble detect by lower case “b” indication in the lower center of the display with the IV Test Set installed.

3.6.10 3860+ Remote Radio Setup

If during repair the IVPAB015 Remote Radio assembly was replaced, the radio will need to be programed before use. Preform the following:

3.6.10.1 Remote Radio Programing:

From Service Mode A Press the (F3) soft key then the (F6) soft key "Load Defaults", note Command, Sent, and Rec. setting will scroll while defaults are loaded. Once Scrolling stops, press (F5) soft key "Store" and verify Rec.: and Sent: display "m>". Press CANCEL key. Power Off (O) key approximately 2 +/- 0.75 second and Power Off the pump.

3.6.10.2 Flow preventer Switch Verification:

Press Power On (I) key, select New Patient and verify normal Pump display.Select channel B with the F6 Key. Open Channel B door, press black pinch clamp in on IV Set Flow preventer assembly, verify Check Door B flashes at top of screen and pulsing alarm sounds within 2 seconds. Note: Flow switch must be On in service menu.

3.6.10.3 Flow Stop Pull Test:

Open door verify black pinch clamp has been fully retracted (Flow stop is closed) and Flow preventer housing is retained in the gray/violet flow stop carrier (IVP1047/AS120).

Note: If pull test fails (black flow preventer not fully retracted) on a new 1000 series IV set, the IVP1068 Door Clamp Clip is worn and should be replaced. Ref: AS112A drawing in Section 5, Assemblies and Drawings.

3.6.10.4 Green Run and Red Alarm LED Verification:

Load a fluid filled set into the pump and close the door. Press Power On (I) key, select New Patient and verify normal Pump display. With the Rate 1.0 highlighted, press Enter again to Select a VTBI of .1. Verify Pump Displays "Unload Set", open the door,remove Fluid filled tubing from Bubble detector at bottom of Pump. Verify Display message changes to "Close Door". Close Door and verify "Close Door Message is removed from top of screen and "Push Start A" is flashing at bottom of screen. Press the start/stop key. Verify Green (run LED) begins flashing. Open the Door and verify Red alarm Led flashes and Speaker alarm sound. Press Alarm Cancel.

3.6.10.5 Sound Adjustment Verification:

Press the Menu Key then press (F3) to select Alarm Volume menu item. With the Up & Down arrow keys verify the alarm volume can be raised and lowered and saved to the appropriate setting.

3.6.10.6 3860+3860+ Remote Radio Verification

Connect 106db attenuator cable from Pump Antenna Connector to Test Remote Antenna Connector or install Antennas on both both Pump and Remote.

3.6.10.7 Press Power (I) on Pump. If New Patient and Same Patient are displayed, press the (F1) soft key to select New Patient to bring up the normal Channel A display. From the normal Channel A display, press MENU key, press (F6) soft key to select Next Menu, press (F5) soft key to select Set Comm. Channel, then press (F1) soft key to select

Channel 1.

3.6.10.8 Press power (I) on test Remote. If "No Communications" displayed, press MENU key, press (F6) soft key to select Next Menu, press (F5) soft key to select Set Comm. Channel, then press (F1) soft key to select Channel 1 and press Enter.

3.6.10.9 Check communication control between Pump and Remote as follows:

3.6.10.9.1 On Remote, press (F1) soft key to highlight Rate, then press Up arrow to set rate to 100 mL/hr, and then ENTER. With VTBI highlighted press Up arrow and set VTBI to 200 mL. Load IV Set in Pump, verify Ready to Start is displayed on both Pump and Remote. Press Start Channel A Remote and verify green (run) LED is flashing on both Pump and Remote.

3.6.10.9.2 Occlude inlet of IV Set above Pump and verify Red Alarm LEDs are flashing and speaker Alarm sounds on both Pump and Remote. Press ALARM SILENCE key on remote, verify Alarm sound is silenced, and Alarm LEDs stop flashing on both Pump and Remote. Press Start Channel A Remote and verify green (run) LED is flashing on both Pump and Remote.

3.6.10.9.3 On Remote, press MENU key. Press (F1) soft key to select Dose Rate Calculation and verify Dose Rate A screen is displayed on both Pump and Remote. Press CANCEL key.

3.6.10.9.4 On Remote press the (F3) soft key to select Alarm Volume. Verify Alarm Volume screen is displayed on Remote and "Adjusting the Remotes' Alarm Volume" is displayed on the Pump. Verify pressing the Remotes' Down arrow key lowers the volume and causes the displayed bar to move to the left of the screen. Pressing Remotes' Up arrow key increases the volume and causes the displayed bar to move to the right of the screen. Return displayed bar to the center of screen, then press the ENTER key.

3.6.10.9.5 On Pump, press the (F3) soft key to select Alarm Volume. Verify Alarm Volume screen is displayed on Pump and Adjusting the Pumps' Alarm Volume is displayed on the Remote. Pressing Pumps' Up arrow key increases the volume and causes the displayed bar to move to the right of the screen. Verify pressing the Pumps' Down arrow key lowers the volume and causes the displayed bar to move to the left of the screen and at lowest alarm volume is still audible. Return displayed bar to the center of

screen, then press the ENTER key.

3.6.10.9.6 Press (F6) Next Menu then press the (F2) soft key to select Occlusion Limit. Verify Occlusion Limit screen is displayed. Verify that pressing the Down arrow key decrements 0.1 psi with each press to 1 psi. Verify pressing the Up arrow key increments 0.1 psi with each press to 10 psi and press Enter key.

3.6.10.9.7 Press the (F6) soft key to select Next Menu. Press the (F1) soft key to select KVO rate. Verify pressing the Up and Down arrow keys selects from 1 to 5 mL/hr for the 3850 and from 0 to 5mL/hr for the 3860+. Return setting to 1 mL/hr., then press the ENTER key.

3.6.11 10 Key Pad Verification (3860+ only)

3.6.11.1 Using 10 key pad with Rate highlighted enter 123, verify tone with each key press and then press enter verifying 123 entered in rate.

3.6.11.2 Using 10 key pad with VTBI highlighted enter 456, verify tone with each key press and then press enter verifying 456 entered in VTBI.

3.6.11.3 Using 10 key pad with Rate highlighted enter 789, verify tone with each key press and then press enter verifying 789 entered in rate.

3.6.11.4 Using 10 key pad with VTBI highlighted enter 900, verify tone with each key press and then, press C and verify VTBI displays 0. Enter 999 Using 10 key pad, then press Enter.

3.6.11.5 Using 10 key pad with Rate highlighted enter 83.2, verify tone with each key press and then press enter verifying 83.2 entered in rate. Press Start A.

3.6.12 SpO2 Verification (3860+ Only)

3.6.12.1 Connect 1170 test F.O. probe to pump. Press Cancel to return to Resume Therapy Screen, verify SpO2 is displayed in lower portion of screen on both Pump and Remote.

3.6.12.2 Connect 1170 test F.O. Probe to Pronk Technologies OxSim, insure IR and Red LEDs are on, and press mode switch to select 98% / 80bpm. Verify Pump displays SpO2 of 98% +/-1 & 80 +/-1 BPM and PI: 4.0 +/- .5%.

3.6.12.3 Press Mode and select 99% Low Perf. Verify Pump and Remote displays SpO2 of 99% +/-1, & 80 +/-1 BPM, and PI: 0.3 +/- .2%.

3.6.12.4 Select New Patient or verify normal Pump display with the Rate 1.0 highlighted. With a rate of 83.2 and VTBI of 999, open Door and insert IV Set filled with water and close Door. Press the START/ STOP key and verify Green (run LED) begins flashing and SpO2 is displayed in the lower portion of the screen on both Pump and Remote.

3.6.12.5 Press Mode and select 98%, 140 bpm. Verify Pump and Remote display SpO2 of 98% +/-1 & 140 +/-1 BPM and PI: 3.0 +/-

.5%.

3.6.12.6 On Pump, press Menu, Next Menu (F6), Spo2 Menu (F4), and HR Hi Limit: (F2). Verify 200 bpm highlighted. With Down Arrow select 130 bpm and press Enter. On both the Pump and Remote, verify "High HR" displayed alternately with battery icon at top of screen, Alarm sound and Alarm LED. Reset HR Hi Limit to 200 bpm. Press ALARM SILENCE and verify "HIGH HR" is not displayed at the top of the screen.

3.6.12.7 Press Next Menu (F6) and select SpO2 menu (F4) and verify SpO2 Low Lim: 85% is highlighted. With Up Arrow select 90% and press Enter twice. With OxSim Mode switch select 85% 80 bpm. Verify Pump and Remote displays SpO2 of 85% +/- 1 & 80 +/-1 BPM, Low SpO2 displayed alternately with battery icon at top of screen, Alarm sound and alarm LED

3.6.12.8 Remove 1170 test F.O. Probe from OxSim and verify Probe Off, Alarm sound and Alarm LED flashing on both Pump and Remote.

3.6.12.9 Disconnect 1170 test probe from Pump and verify No Probe is displayed alternately with battery icon at top of screen, Alarm sound and Alarm LED. Press Alarm Silence and verify Alarm reset and SpO2 removed from screen on both Pump and Remote.

3.6.12.10 3861 SideCar Verification :
Install Test 3861 Side Car on Pump if SideCar is to be used with pump. Press Pump (I) key and verify Pump Power is On. Resume Therapy screen appears, press Same Patient. Select Channel B and verify the following:

3.6.12.10.1 Press Channel B (F6) soft key, press (F1) soft key, set Rate of 83.2 and press ENTER. Press Up arrow and set VTBI to 999 on start Channel B. Unload set if necessary and ensure "Ready to Run B". Press START/STOP Channel B, and verify Green (run LED) begins flashing on SideCar.

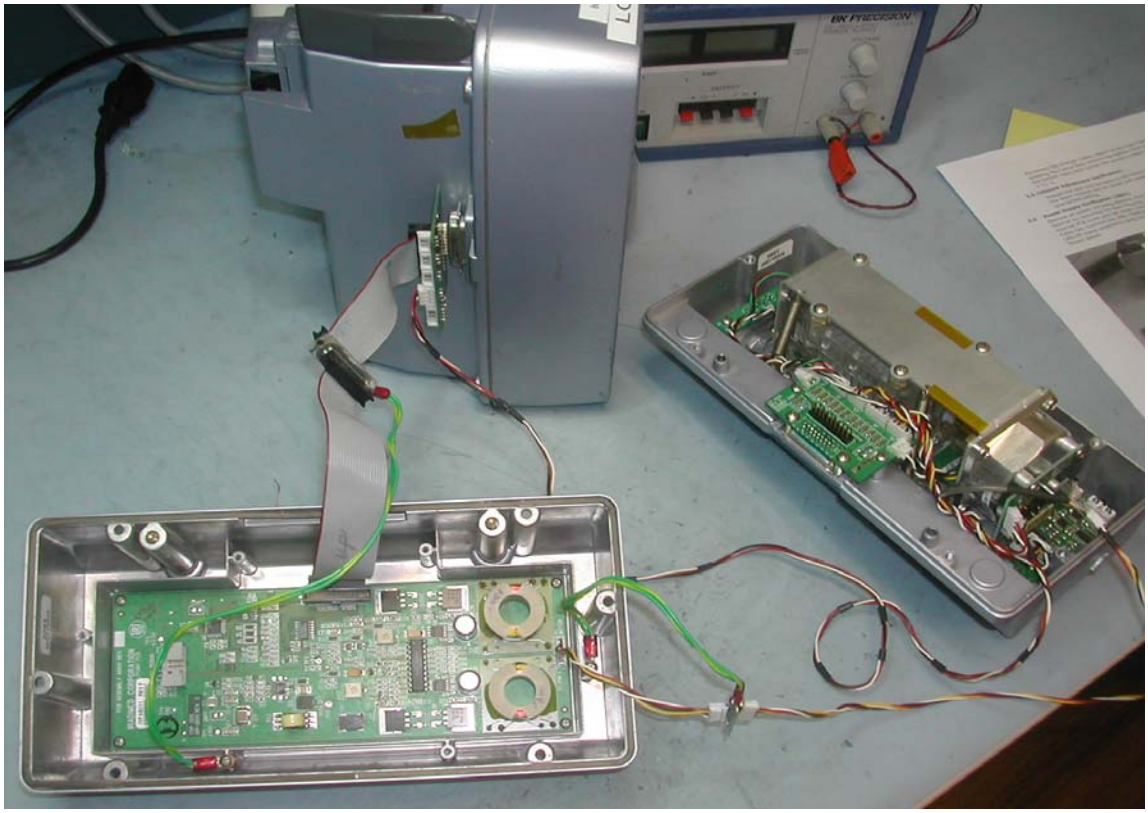
3.6.12.10.2 Occlude outlet line below SideCar Pump and verify Red alarm LED on SideCar flashes and Speaker Alarm sounds and message "PT Occluded B" flashes on the screen.

3.6.12.10.3 Press (0) Power Off key for 2 seconds to Power off Pump. Press and hold the CANCEL key and press the Power On (I) key to enter Service Mode. Press START/STOP Channel B key, verify Service Mode B is now displayed. With IV Set installed, verify small "b" at bottom of screen. Remove IV Set and verify large "B" at bottom of screen. Press (0) Power Off key for 2 seconds to Power Off Pump. Remove Battery, then remove 3861 Test SideCar.

3.7 MRidium Side Car Verification (3861)

Remove all power, including Battery, from the 3860+ Pump. Open the 3861 SideCar by removing the Rear Housing. Remove and disconnect the rear internal PCB cover and set aside. Connect the IVPAB009 PCBA & Test Adapter

Cable Set. Connect the 3861 SideCar rear (IVPAB011) to the 3861 front (AS100 pump assembly) using the SideCar Pump Test Adapter Cable Set as Shown below, being sure to connect filter plate ground clips to rear chassis. Without the Test Adapter Cable Set, alternative connection may be made by directly mounting the Side Car front chassis to the Pump connection port (3860+ left side facing rear) and extending the cables as best as possible to the motor and 20pin ribbon through the PCB cover/RF filter. Newer models of 3851/651 are supplied with small holes through the PCB cover to directly reach the trim pots below for easier motor adjustment.



WARNING: When connecting and disconnecting the gray ribbon cable the IVPAB011 board all power must be removed (Battery and DC charger disconnected from pump). It is recommended to use battery power only during this testing. Connections made with power available may severely damage the IVPAB011.

With the Battery re-installed in the 3860+, verify the following:

3.7.1 DC Input Verification (3861)

(Reference IVPAB011 assembly drawing in section 5.)

Press Keypad On (I) button. Verify and record the following.

1. IVP-AB011 TP 1 is 11.75V +/- 0.5V
2. IVP-AB011 TP 2 is 4.95V +/- 100mV
3. IVP-AB011 TP 3 for 3.3V +/- 75mV

Press Keypad Off (0) button for 2 Seconds.

3.7.2 Pump Motor Speed Adjustment (3861)

Place Pump into Service Mode by pressing Keypad On (I) button and holding the CANCEL key depressed until the Service Mode is displayed. Select Channel B by pressing the Channel B START/STOP key to select SERVICE MODE B.

3.7.2.1 Set R41 (feedback) fully CW. R57 (frequency) fully CCW, R52 (speed) fully CCW. Scope Setup: Channel 1, Sweep Speed to 2ms, 100v/division. Channel 2, Sweep Speed to 2ms, 2v/division.

3.7.2.2 Select MANUAL PUMP RUN, press and hold ENTER on Keypad (100% duty cycle). Adjust R57 CW until speed begins to increase or speed reaches approximately 60-70 RPM. Ensure motor is running CCW (when viewed from the motor end).

3.7.2.3 Adjust R41 fully CCW and note speed is above 240 RPM. Then Reduce speed by turning R41 CW until speed reaches 130~150 RPM.

3.7.2.4 Connect Channel 1 (set to 100V/Div) to PJ5R Pin 1 on IVPAB011 board. Connect Channel 2 (set to 2V/Div) to Encoder output A (J1 pin 3 of the IVPAB043 or P1 pin 3 of the IVPAB003 Board) sync on Channel 2. Select index and press enter. Verify motor goes to index. Select Rate and set to 20, press Start/Stop A. Adjust R57 drive pulse Channel 1 to 4~8ms. Ensure that Channel 2 is measuring 2 pulses (tics). Monitor the lower left counter on the display (displays encoder position from 0 to 1000), verify at least three revolutions. Insure encoder position count rolls over at 1000 back to 1, count should not count more than 2 tics above 1000.

3.7.2.5 If counter is greater than 1002 before it rolls over to 0, readjust R57 (may require more than 8 ms). Press Start/Stop A Key.

3.7.2.6 Verify speed is still at 130~150 RPM, by selecting Manual Pump Run and press Enter.

3.7.2.7 Select MANUAL PUMP RUN with the arrow keys and depress and hold the ENTER Key. With Scope Amplitude to 100V / division and connect Channel 1 to PJ5R pins 1 and 5. Verify >300 P-P and > 100V RMS and frequency is 44.5 KHz +/-2.5 KHz.

3.7.3 Service Mode Display Verification (3861)

Select Manual with the arrow keys and depress the ENTER Key.Verify motor runs and Green LED flashes.Verify speed is displayed in bottom right hand corner @ 135 RPM +/-20 RPM. If speed is outside this range, open SideCar and repeat steps in 3.6.2 Pump Motor Speed Adjustment (3861) above.

3.7.4 Verify Bubble Detect:

With no IV Test Set installed, verify Bubble detect indicated by upper case "B" in the lower center of the display.

3.7.4.1 3861 Pressure Verification:

See Figure 1:Pressure test set made using a portion of the IVP1056 in section 3.2.4.

3.7.4.1.1 Tare Offset Verification:

Connect Pressure Gauge with Hand Bulb to a circular IV Test Set (no fluid) and with Hand Bulb open (0 PSI) See photo below. Open Door, Load IV Test Set, Close the Door and verify pump moves to index, press the F1 key, then press the F4 key (Tare Offset). Press the Cancel key to return to the Service Mode display and verify P3 and P4 are 0 +/- 0.5.

3.7.4.1.2 Pressure Verification:

Close Pressure Gauge Hand Bulb and apply 5.0 PSI per Pressure Gauge. Verify P3 and P4 displays 5 +/- 0.5.

3.7.4.1.3 Pressure Adjustment:

If P3 and P4 did not display 5 +/- 0.5, ensure pressure gauge remains at 5.0, press the F1 Key (top left white key) to enter the Calibrate Pump screen, then press the F5 key (Span Cal). Press the Cancel key to return to the Service Mode display and verify P3 and P4 are now 5 +/- 0.5.

3.7.4.1.4 Zero Verification after Adjustment:

Open pressure gauge hand bulb and verify P3 and P4 now read 0 +/- 0.2. Repeat Tare Offset and Pressure Adjust until P3 and P4 reads displays 5 +/- 0.5 with 5 PSI applied and are 0 +/-0.5 with hand bulb open (0 pressure applied).

3.7.4.1.5 Bubble Detect Verification:

With no IV Test Set installed verify Bubble detect indicated by Upper case "B" in the lower center of the display.

3.7.4.1.6 Verify No Bubble Detect:

Load a IVP1056 set filled with fluid and verify no Bubble detect s indicated by Lower case "b" in the lower center of the display with the IV Test Set installed. Power Off (O) key approximately 2 +/- 0.75 second and Power Off the pump.

3.7.4.1.7 Flow preventer Switch Verification:

Press Power On (I) key, select New Patient and verify normal Pump display.Select channel B with the F6 Key. Open Channel B door, press black pinch clamp in on IV Set Flow preventer assembly, verify Check Door B flashes at top of screen and pulsing alarm sounds within 2 seconds. Note: Flow switch must be **On** in service menu.

3.7.4.1.8 Flow Stop Pull Test:

Open door verify black pinch clamp has been fully retracted (Flow stop is closed) and Flow preventer housing is retained in the gray/violet flow stop carrier (IVP1047/AS120).
Note: If pull test fails (black flow preventer not fully retracted) on a new 1000 series IV set, the IVP1068 Door Clamp Clip is worn and should be replaced.
Ref: AS112A drawing in Section 5, Assemblies and Drawings.

3.8 Pump Calibration (3860+ and 3861)

From the service mode screen the Calibrate Pump Screen is accessed by pressing the F1 (top function key on the left side of the display screen). This screen is for displaying current pump calibration settings.

The Delay setting should be recorded for future reference should a repair action cause loss of this Delay setting. This Delay setting is found during factory calibration with the pump connected to a high accuracy calibrated scale (Sartorius GD603) while the delivery profile at 1 ml/Hr is studied by internal calibration software. Anytime the mechanical alignment of the encoder wheel relative to the pumping finger position is changed or suspect (pump block or motor replaced), this calibration process must be performed.

The following is a description of the Pump calibration normally performed at the factory on both the 3860+ and 3861 products. It is highly recommended that should the 3860+ pump or 3861 SideCar require this calibration, that it be returned to the factory.

If Calibration of pump is made in the field you will need a Sartorius GD603 and the SartoConnect software located in the Calibration Software Folder of the 1125 Service CD.

3.8.1 Factory Pump Calibration:

Spike a vented bottle or bag of distilled water with a Vented/Non-vented Administration Set (Check that the Roller Clamp is closed), hang on the IV Solution Test Stand, prime the Set by opening the Roller Clamp, flushing all air from IV Set. Note: IV Set must be changed at least once per week. Ensure IV Set soft Silicon tubing is 5.75 +/- 1/8 inches long. Connect patient end of IV Set to Sartorius Scale. Install the Administration Set into the 3860+/3861 to be calibrated and latch the Door. Press and hold the CANCEL key, then press the Power On (I) key to enter Service Mode.

3.8.1.1 Raw Curve Verification and Adjustment

Connect Scale RS232 Cable to I/O port at rear of Pump and RS232 port of computer. Open Pump Door, select F1, and set offset so the Pump Fingers are peaked four fingers from the bottom of the Pump, when Pump is at index. Close Door. Using SartoConnect data collection program select Data Output, then Configuration Data, Application ASCII-Datei, select "---" tile, again select ASCII-Datei, select "---" tile,

name file(SN_Raw_Date), click Open, then click Save. Click Start SartoConnect data collection program and Select Calibrate on Pump and press ENTER. This test will take 10 to 20 minutes. When scale reading reads greater than 0.07 grams press Stop on SartoConnect data collection program. Using Microsoft Excel, open saved file and line graph data by highlighting time and weight columns form 0 to 0.07. Verify Raw Curve will allow calibration. Ideal Raw Curve is shown in Figure A. If Curve shows too much taper (see Figure B), shims must be added to top pump standoffs. Verify Raw Curve will allow calibration. Ideal Raw Curve is shown in Figure A. If Curve shows too much taper (see Figure B), shims must be added to top pump standoffs. If Curve shows not enough taper (see Figure C), shims must be added to the bottom pump standoffs (motor end of pump). *Note: .003 shim will move curve step approximately .0033.* Once curve is similar to figure A, perform Pump self

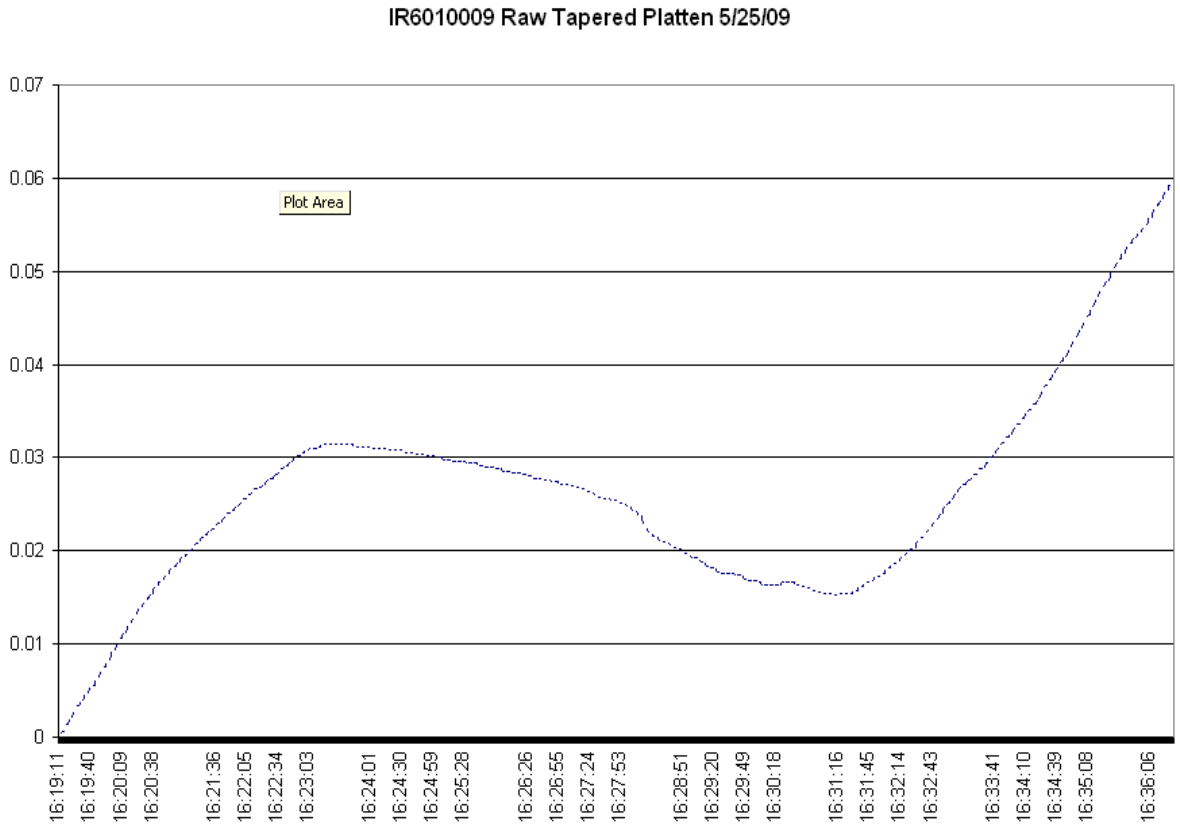


Figure A: Ideal Taper Raw Curve 3860+/61

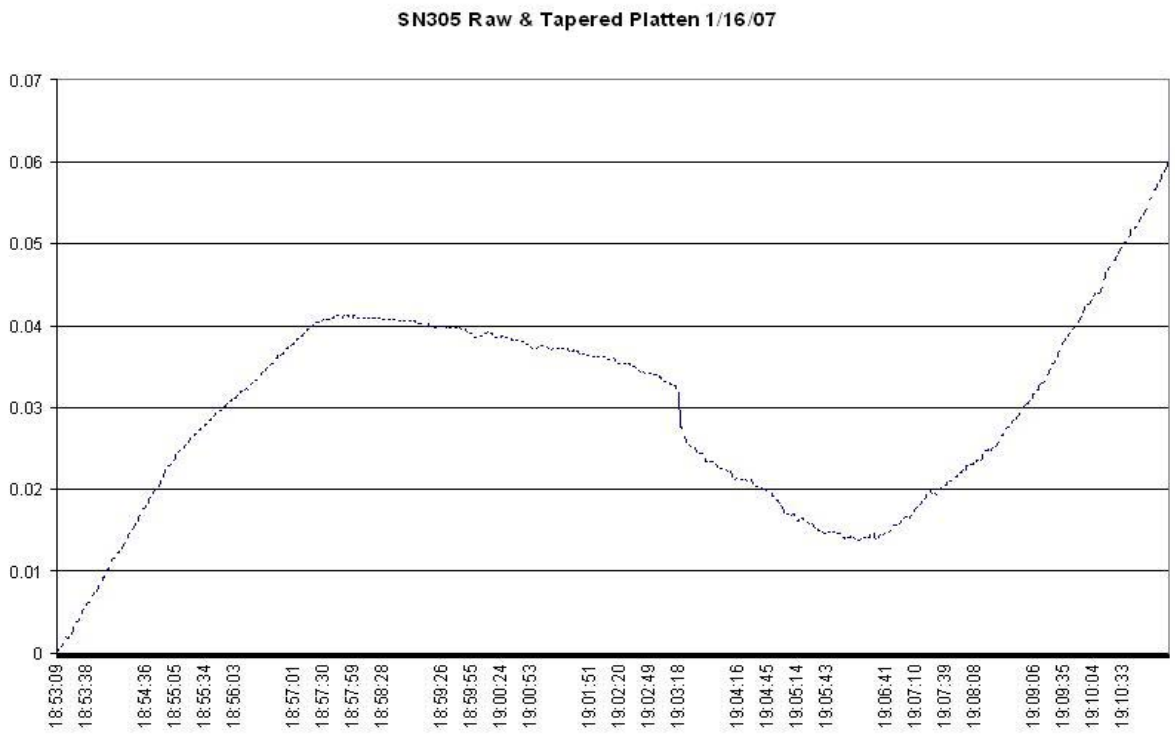


Figure B: Too Much Taper Raw Curve 3860+/61

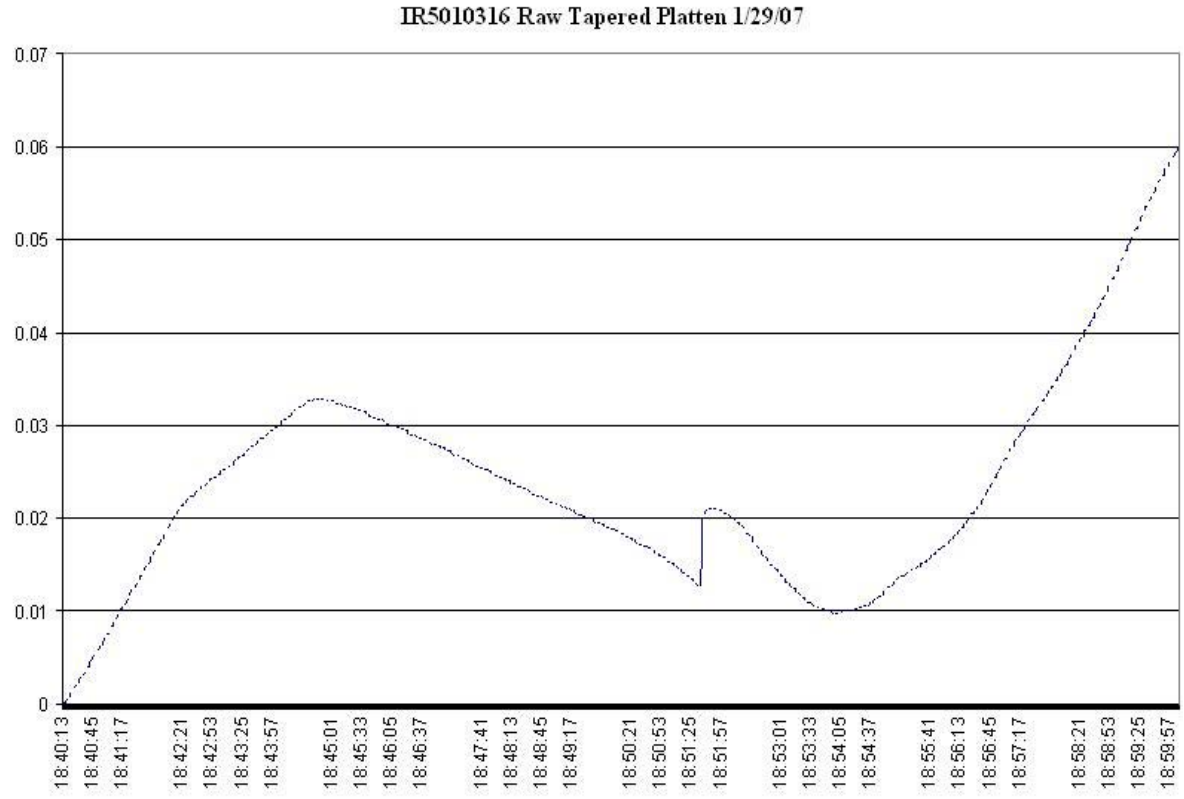


Figure C: Not Enough Taper Raw Curve 3860+/61

3.8.1.2 Auto Pump Calibration and Flow Correction

Click T SartoConnect data collection program, verify Scale is now at 0. Connect Scale RS232 cable to I/O port at rear of Pump. Note Scale #s and 255 displayed on first line at bottom of display indicating Scale connection. Choke inlet with forceps, select and press to index twice, then select the "Calibrate" option, press the ENTER key, and let Pump run until the 255 displayed beside the Scale #s changes to 99 indicating Cal. complete. Remove forceps from inlet. With the arrow keys, select Move To Index and press ENTER twice. Note tic count.

Press the (F1) soft key, note delay and verify delay is within 2 tics of previously noted tic count after Move To Index.

Verify 'Comp.:' is at 0.0%. Press (F2) soft key and verify Pump begins running. Pump will now run for approximately 5 minutes. When Pump stops, Comp.: changes to a new value, press CANCEL key and verify successful Comp. cal. as indicated by 100 displayed next to Scale numbers.

Self Calibration Status Codes

0 - Initial Value, not run yet.

255 - Calibration running.

99 - Encoder calibration complete

98 - Compensation calibration failed: out of bounds.

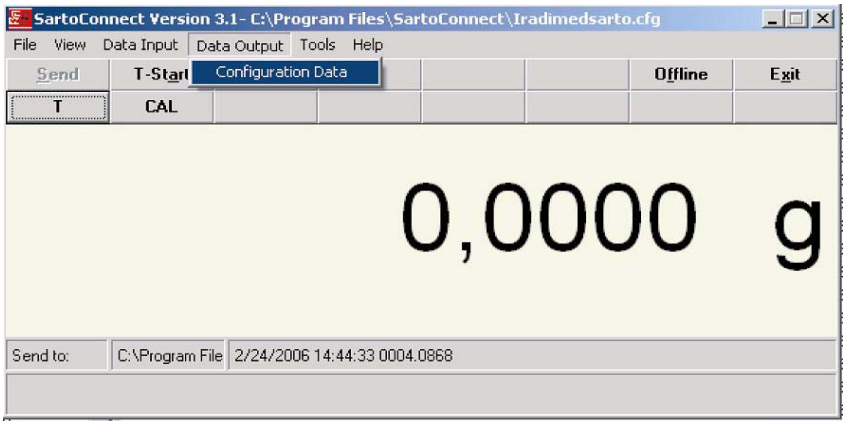
100 - Compensation calibration complete.

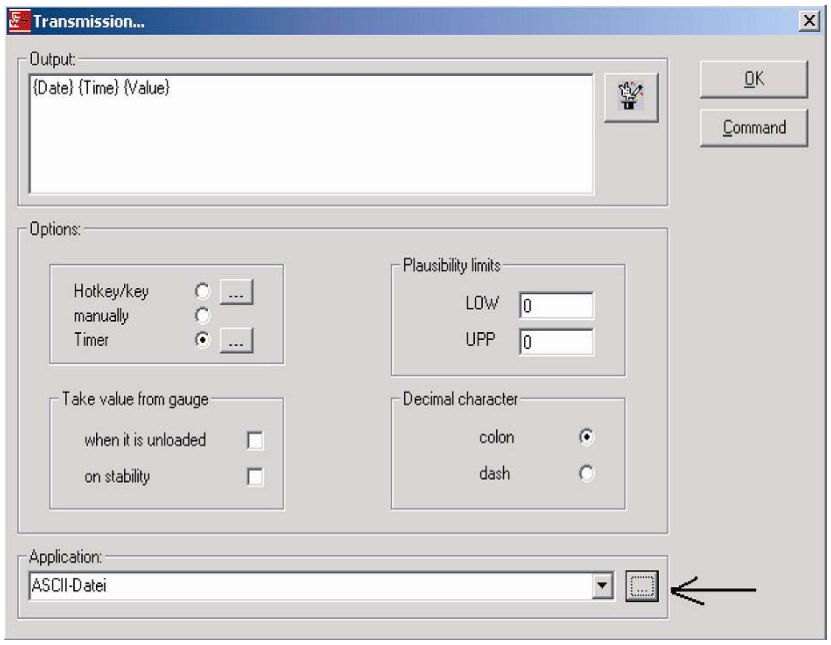
15 - Calibration failed: sudden mass increase (table bumped?)

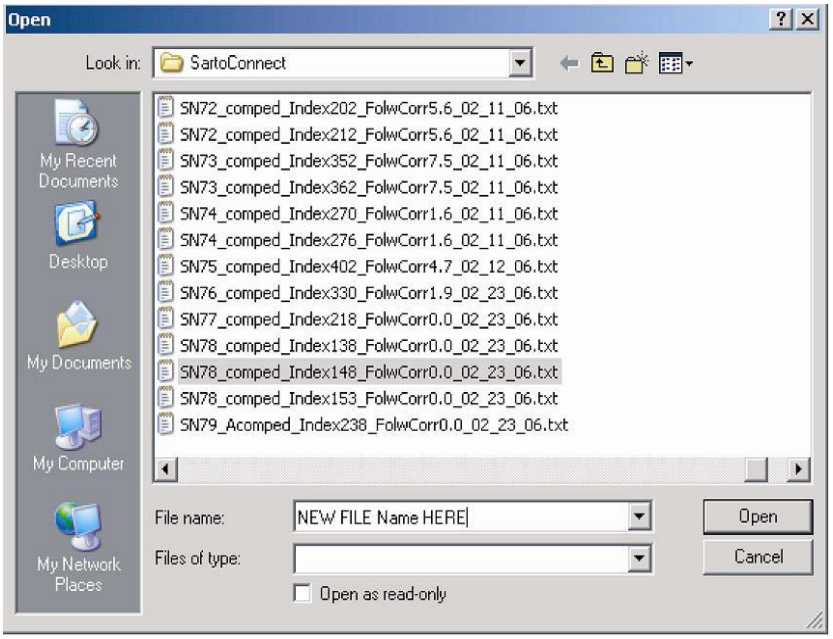
All other codes: Various communication errors, check cabling.

3.8.2 Calibration Verification.

Connect Sarto Scale to PC. Using SartoConnect data collection program select Data Output, then Configuration Data, Application ASCII-Datei, select "---" tile, again select ASCII- Datei, select "---" tile, name file, click Open, then click Save. Note: On display below, comma represents a decimal point.







On Pump, select Index and press ENTER, again on Pump select Rate; 1.0, ensure SartoConnect is Online (Offline showing in tab), zero Scale with T-tab on SartoConnect, start data collection (select T-Start), and press START on Pump. Monitor Scale and stop Pump after 0.06 g is displayed on Scale window. Select TStop on SartoConnect.

Using Microsoft Excel, open the saved file and line graph data by highlighting the time and weight columns. Verify step is less than 0.0075g for 3860+ (ref. Figure D) or .0025g for 3860+ (ref. Figure E). If step is greater than 0.0075g for 3860+ or .0025g for 3860+, offset may be adjusted +/-10 to 15 counts to obtain desired results. If manual adjust is necessary, be sure to rename file and title with SN xxx comped w/ Manual Adjust Index @ (new index) with date.

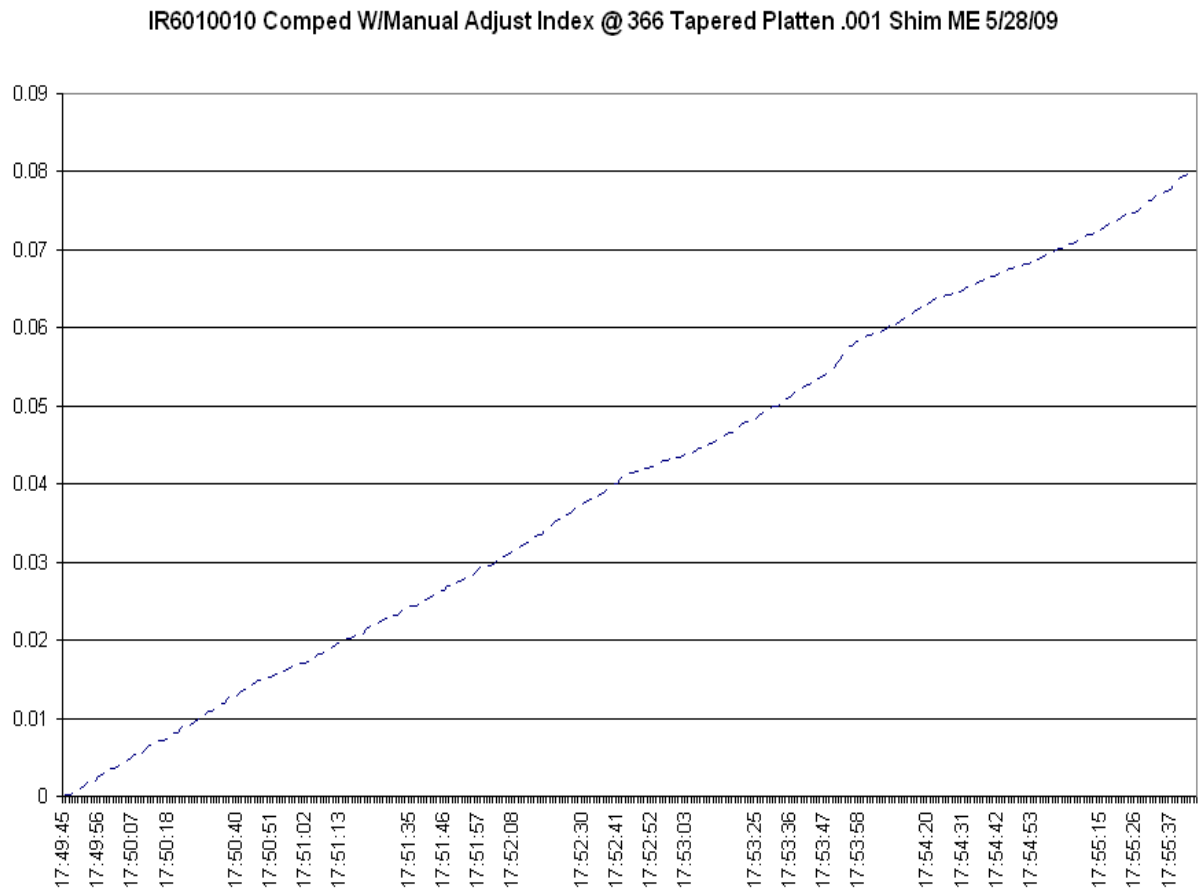


Figure D: 3860+ Comped Curve

3.8.3 Pump Accuracy Verification (3860+ and 3861):

Restart the unit in normal mode. Using IV Set 1056 insert set spike into water container and hang water container approximately 21 inches above MRidium 3860 MRI Infusion Pump. Squeeze drip chamber to fill approximately 2/3 full. With Free Flow Restrictor pinch clamp open prime tubing and clear air by slowly open roller clamp allowing water to fill tubing.

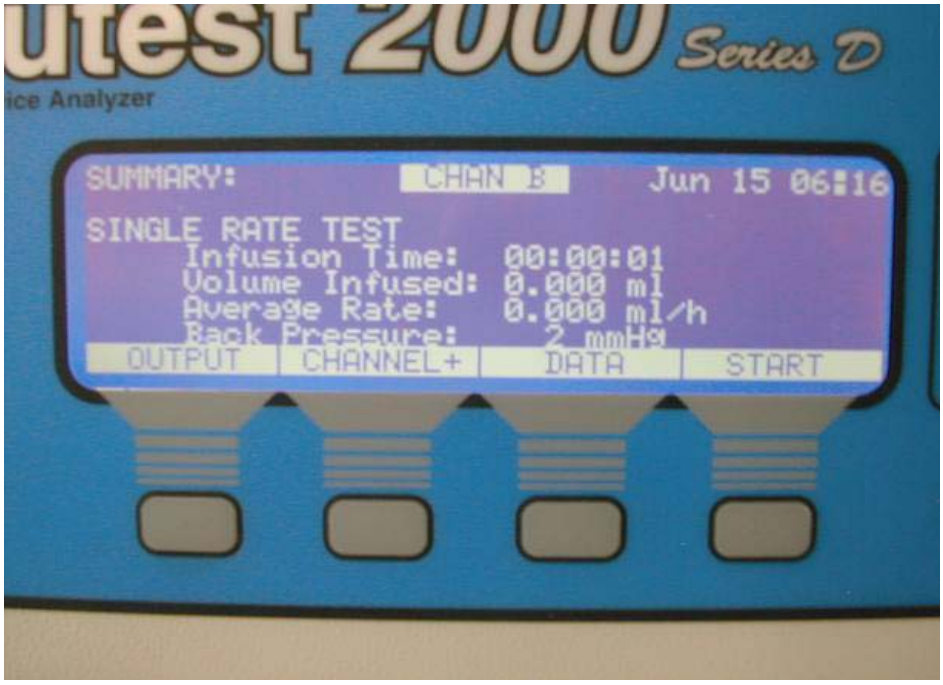
Install IV Set in 3860+ pump or 3861 SideCar as shown below and close door:

3.8.3.1 Infutest 2000

Connect patient end of IV Set to Infutest 2000 as shown below to either Channel A or B as desired and set the other channels stop cock to off as shown on following page:

Ensure that Infutest 2000 Flush Syringe has approximately 60 cc of water, connect IV Set to right side as shown above (the long 21 gauge flow restrictor side), with stop cock position as shown run Pump for a short time to flush all air bubbles past stop cock.

Select channel, and press start, as shown below.



With Set Test ensure "Test: Single Rate" as shown below.

Rotate Flush syringe Stop to Prime Position and inject about 5 cc of water into the channel over about 5 seconds. Note the Infutest reminds the user to do this via the LCD prior to starting each test.

Return the Stop Cock to the Test Position.

3.8.3.2 Occlusion Limit Verification

Set Pump Rate to 100 mL and VTBI to 100 mL. Press MENU key and select Occlusion Limit (F3) soft key and verify that Occlusion Limit is set to 10 psi. On Infutest 2000, with SET TEST Menu selection, set TEST to Occl. Press START on Pump and Go on Infutest 2000. Monitor Time on Infutest 2000, and verify "Patient Occluded A" Alarm on Pump in 40 seconds or less.

Set Pump Rate to 100 mL and VTBI to 600 mL, verify Ready to Start is flashing in lower right of the display. Press the START/STOP Channel A key and verify the Pump begins running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door. Press Go on the Infutest 2000. Allow Pump to run for 5 minutes. Press Stop on Infutest 2000. If Avg. Flow on Infutest 2000 display is not 100 +/- 2%. Press and hold the CANCEL key and press the Power On (I) key to enter Service Mode. Select (F1) soft key, press ENTER, and with Comp. highlighted adjust Comp. up or down to correct flow rate. Press ENTER, CANCEL, then (F1) soft key to verify adjustment. Power Off & back On, select Same Patient and repeat above flow test. Once 100mL flow is within 2%, set Pump to 10 mL and repeat flow test, but allow Pump to run 10 minutes. Again adjust Comp. if necessary. Verify 10 mL flow +/- 2%.

Set Pump Rate to 1 mL and VTBI to 10 mL, verify Ready to Start is flashing in lower right of the display. Press the START/STOP Channel A key and verify the Pump begins running as indicated by the pulsing ">" display and Green flashing LED in the top of the Door. Press Go on the Infutest 2000. Allow test to run for a minimum of 2 hours. After the test runs Over 2 hours (two or three minutes over), press Stop on the Infutest 2000.

Note: Do not press Start again or the test run of 2 hours of data will be lost.

If 4 Pumps are run overnight, select the PC's Tera Term Program Icon. From the Tera Term Program select Setup, then select Restore Setup, then select Infutest.ini (double click), again select Setup, then select Serial Port, and verify Com-4 is selected. If not, select Com-4 and click OK.

Start all Pumps running at 1 mL. Flash and start all channels of Infutest 2000, insuring that all channels are set to Single Rate Test. Once all channels are started on Infutest 2000 select Control on Tera Term Program, then select MACRO and double click on Infutest_st.ttl. MACRO - Infutest_stop.ttl (available from Iradimed) should appear at the bottom of the screen indicating the program Macro will stop all channels of

the Infutest 2000 after 6 hours. (Note: this is necessary because the Infutest 2000 only has 6 hours of memory data and the 1st 6 hours of data is required. The 2nd hour of data must be used for Trumpet verification.

Connect Infutest 2000s serial port (DB25) to PC Com-1 port of personal computer with Infutest DTP program installed. Double click the DTP icon on the computer desktop screen to bring up the Data Transfer program. Click File, then Download, select Channel (A or B), Mode "Get Log", and click "OK". Enter File Name with serial number of Pump tested, 1 mL 2hr, and Date. Example: "SN10_1mL_2hr_7_16_05". Click Save and then fill in Manufacturer, Model, Serial No., Department, & Set Rate. Click Continue and wait for file to be downloaded. When download is complete, click "Save".

From the DTP main program window, click "File", then "Graph Data Log". From the Graph Data Log Menu select File then Open. Locate the file you just saved, select it, and click Open. From the Data Log window that opens, select File, then Trumpet Graph. From the next window click "OK" (ensure both Calculation Window & Start Time are at their default settings of 60). The Trumpet should now be displayed. Click the Scale Menu icon button until the Trumpet is within the graph plot, then select Print. Verify Average Flow Rate is 1 mL +/- 3%.

Verify the Max: of the "2" Observation Period is less than 50% and Min: of the "2" Observation Period is less than -50%. Verify the Max: and Min: of the "32" Observation Period is less than +/- 3%.

3.8.3.3 1400 ml Flow Rate Test

Select Cancel Infusion with the bottom function key on the Pump. Set the Pump Rate to 1400 mL/hr., & VTBI >600mL.

Press Start on the Infutest 2000 and rotate flush syringe stop to Prime position and inject about 5 cc of water into the channel over about 5 seconds. Return stop to Test position.

Verify Ready to Start is flashing in lower right of the Pump display. Press the START/STOP Channel A key and verify the Pump begins running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door.

Press Go on the Infutest 2000. Allow Pump to run for a minimum of 2 minutes, then press Stop on the Infutester. Verify Average Flow Rate is 1400 mL +/- 3% and record.

3.8.3.4 999 ml Flow Rate Test

Select Cancel Infusion with the bottom function key on the Pump. Set the Pump Rate to 999 mL/hr., & VTBI >500mL.

Press Start on the Infutest 2000 and rotate flush syringe stop to Prime position and inject about 5 cc of water into the channel over about 5 seconds. Return stop to Test position.

Verify Ready to Start is flashing in lower right of the Pump display. Press the START/STOP Channel A key and verify the Pump begins running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door.

Press Go on the Infutest 2000. Allow Pump to run for a minimum of 2 minutes, then press Stop on the Infutester. Verify Average Flow Rate is 999 mL +/- 3% and record.

3.8.3.5 500 ml Flow Rate Test

Select Cancel Infusion with the bottom function key on the Pump. Set the Pump Rate to 500 mL/hr., & VTBI to 62 mL.

Press Start on the Infutest 2000 and rotate flush syringe stop to Prime position and inject about 5 cc of water into the channel over about 5 seconds. Return stop to Test position.

Verify Ready to Start is flashing in lower right of the Pump display. Press the START/STOP Channel A key and verify the Pump begins running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door.

Press Go on the Infutest 2000. Allow Pump to run for a minimum of 2 minutes, then press Stop on the Infutester. Verify Average Flow Rate is 500 mL +/- 3% and record.

3.8.3.6 125 ml Flow Rate Test

Select Cancel Infusion with the bottom function key on the Pump. Set the Pump Rate to 125 mL/hr., & VTBI >200mL.

Press Start on the Infutest 2000 and rotate flush syringe stop to Prime position and inject about 5 cc of water into the channel over about 5 seconds. Return stop to Test Position.

Verify Ready to Start is flashing in lower right of the Pump display. Press the START/STOP Channel A key and verify the Pump begins running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door.

Press Go on the Infutest 2000. Allow Pump to run for a minimum of 5 minutes, then press Stop on the Infutester. Verify Average Flow Rate is 125 mL +/- 3% and record.

3.8.3.7 25 ml Flow Rate Test

Select Cancel Infusion with the bottom function key on the Pump. Set the Pump Rate to 25 mL/hr., & VTBI >100 mL.

Press Start on the Infutest 2000 and rotate flush syringe stop to Prime position and inject about 5cc of water into the channel over about 5 seconds. Return stop to Test position.

Verify Ready to Start is flashing in lower right of the Pump display. Press the START/STOP Channel A key and verify the Pump begins running as indicated by the pulsing ">" in the

upper portion of the display and Green flashing LED in the top of the Door.

Press Go on the Infutest 2000. Allow Pump to run for a minimum of 10 minutes, then press Stop on the Infutester. Verify Average Flow Rate is 25 mL +/- 3% and record.

3.8.3.8 0.4 ml Flow Rate Test

Select Cancel Infusion with the bottom function key on the Pump. Set the Pump Rate to 0.4 mL/hr., & VTBI >10 mL.

Press Start on the Infutest 2000 and rotate flush syringe stop to Prime position and inject about 5cc of water into the channel over about 5 seconds. Return stop to Test position.

Verify Ready to Start is flashing in lower right of the Pump display. Press the START/STOP Channel A key and verify the Pump begins running as indicated by the pulsing ">" in the upper portion of the display and Green flashing LED in the top of the Door.

Press Go on the Infutest 2000. Allow Pump to run for a minimum of 30 minutes, then press Stop on the Infutester. Verify Average Flow Rate is 0.4 mL +/- 8% and record.

3.8.4 History Verification (3860+)

Return to Service Mode by pressing the overlay KeyPad On (I) button and the holding the overlay KeyPad Cancel key depressed until the service Mode is displayed. Now select the SERVICE MENU by pressing the F3 soft key (third key down on left side of screen). Press History Log when the following is completed.

Before selecting this menu option, the pump must be connected to a PC with a standard RS232 cable (no connection on pins 1,6,8,9;2-2,3-3,4-4,5-5 & 7-7) and a terminal program running ready to receive. Set your terminal program as follows:

Baud rate: 1200.
Data: 7 bit.
Parity: none.
Stop: 1 bit.
Flow Control: none.

Note: We use “Tera Term Pro” included on Service Manual CD in Calibration Software Folder.

Reference Section 2, paragraph 2.1.3.2 and verify History Log.

Note: History Log may be cleared if desired, see section 2 paragraph 2.1.1.

3.8.5 Radio Verification (3860+ and 3865):

Connect 2.4 GHz antenna and AC Power Cord to 3865 Remote Display Charger. Verify MRidium™ 3860+ MRI IV Pump has Remote Radio Option installed. And perform the following:

3.8.5.1 Turn both 3860+ Pump and 3865 Remote Display/Charger on.

3.8.5.2 Press the Menu key on the Remote Display/Charger

3.8.5.3 Press the NEXT MENU soft key to bring up additional menu options, then press the Set Comm Channel soft key.

3.8.5.4 From the Radio Channel menu, select the desired Channel 1 through 6 by pressing the soft key next to that channel and verify that Channel is now highlighted.

3.8.5.5 Press the Menu key on the MRidium 3860+ MRI IV Pump.

3.8.5.6 Press the NEXT MENU soft key to bring up additional menu options, then press the Set Comm Channel soft key.

3.8.5.7 From the Radio Channel menu, select the same Channel that was selected for the Remote by pressing the soft key next to that channel and verify that Channel is now highlighted.

3.8.5.8 Add an ID marker on both the Remote and Pump with the Channel selected.

3.8.5.9 Verify communication between Remote and Pump by pressing the Menu key on one and the Cancel key on the other, and observing both display match and change simultaneously.

NOTE: Each pump ships from the factory with a default setting of 63 mW (+18 dBm) and at this level will penetrate most MRI magnet screen rooms. Some MRI magnet screen rooms are tight enough to require the maximum power level setting of 250 mw (+24 dBm).

To increase the power level to maximum reference paragraph 2.1.3.3 and change command "wp" from 01 to 02.

A simple test of radio link robustness can be conducted utilizing the 'open field' method. The pump and remote and be separated by 100 feet and verify proper remote control operation. Notice that while scrolling numeric values, the numbers roll smoothly will little pause or delay and that the link lost alert is not triggered. Should the above test fail, check the antenna and internal antenna cable (AC28) for damage.

3.9 Power Supply verification (3865)

(Reference IVPAB013 assembly drawing in section 5.)

Additional Test Item needed: TF009 Battery Simulator Assembly and cables.

3.9.1 DC Input Verification (3865)

3.9.1.1 Connect Line Power to 3865, measure DC output from power supply between J5 pins 1 (Gnd) & 2 (+V) on the IVPAB013. Adjust DC supply for 19V +/- 0.5V at IVPAB013, J5-2.

3.9.1.2 Press Keypad On (I) button. Verify and record the following: IVP-AB013 TP 1 is 5V +/- 75mV. IVP-AB013 TP 2 for 3.3V +/- 75mV

3.9.1.3 Press Keypad Off (0) button for 2 Seconds.

3.9.2 Battery Charger Verification (3865)

3.9.2.1 Connect Battery Simulator TF009 to P1 BATTERY connector, connect DC Power Supply to J5 POWER IN connector. Connect meter to measure Amps into Battery Simulator (This is the DC Power Supply current). Insure TF009 Battery Simulator Load Knob is fully counter-clockwise. Set DC Power Supply to 19 VDC. Adjust Battery Simulator Load Knob clockwise until charge current flows. Verify Power LED is lit Green and changes to Yellow (or Amber) when charge current begins to flow.

3.9.2.2 Adjust Battery Simulator Load Knob fully clockwise for maximum charge current. Verify current 1.4A +/-0.2A and Power LED remains Yellow (or Amber).

3.9.2.3 Adjust Battery Simulator Load Knob for 0.5A and adjust CHRG Pot R89 for 16.82 +/-0.01V at P2-2.

3.9.2.4 Turn DC Power Supply OFF, disconnect Battery Simulator cable from P1 BATTERY connector and DC supply from J5 connector**.** Reconnect 3855 Power Supply.

3.9.3 Line Power Verification Test (3865)

3.9.3.1 Nominal Line Power Verification; With Battery Simulator still connected and set to maximum charge current, connect Autotransformer to the 3865 to be tested and set Autotransformer to 117 VAC nominal line voltages. Power on Unit, record and verify IVPAB013 J5-2 is 19V +/-0.5V.

3.9.3.2 Low Voltage Verification; Set autotransformer to 85 VAC ±1.0VAC line voltages. Power on Unit, record and verify IVPAB013 J5-2 is 19V +/-0.5V.

3.9.3.3 High Voltage verification; Set Autotransformer to 264 VAC ±1.0 AC line voltages. Power on Unit, record and verify IVPAB013 J5-2 is at 19V +/-0.5V. Disconnect Battery Simulator cable from P1 BATTERY connector and reconnect 3865 battery cable to P1. Return Autotransformer to 117VAC nominal line voltage and/or connect 3855 to be tested AC input to normal line power.

3.9.4 Initial Power-Up Verification (3865)

Hold (F1) soft key depressed and press Front Panel On (I) switch and verify the following initial display:

IRI LOADER FLASHER

© 20XX

MS03 XXXXXX XXXXXX (where X is current revision)

NO CARD DETECTED

Record MS03 revision. Release the (F1) soft key and verify:

Powering On

X.X.XXXX (where X.X.XXXX is current revision)

Record this revision as MS07 and verify it is followed by:

No Communication Display With Battery Icon

3.9.4.1 Verify Power Off requires a 2 second depression of the Power Off (0) key.

Figure 3-4.

3.9.4.2 Software Load Verification**;** Insert DataFlash Program Card (AM04) in card slot at bottom of 3865 (see Figure 3-2). Depress Power On (I) key and verify card is detected and the following is displayed:

IRI LOADER FLASHER
© 20XX
MS03 XXXXXX XXXXXX (where X is current revision)
CARD DETECTED
UPDATING MSTR PROC
VERIFYING ERASE
ERASE OK
FLASHED (COUNTING TO 100%)
VERIFYING (COUNTING TO 100%)
MSTR VERIFY OK
FLASHING SUCCESSFUL

3.9.4.3 Verify "No Communication Display" follows "Flashing Successful". Remove Flash Card and turn power Off (0).

3.9.4.4 WIT2450 Radio Firmware Revision and Serial Number: Press and hold CANCEL and press the Power On (I) key to enter Service Mode. Press the (F3) soft key to enter the Service Menu and then press the (F3) soft key again to enter the Configure Radio Menu. From the WIT2450 banner "WIT2450 v x.xx Cirronet : Base xx xx xx", record the

"v" firmware version. Press (F6) soft key; "Load Defaults", note Command, Sent, and Rec. setting will scroll while defaults are loaded. Once Scrolling stops, press (F5) soft key "Store" and verify Rec.: and Sent: display "m". Press the CANCEL key and set Keylock Enable; insure that Keylock is also enabled on 3860 Pump.

3.9.5 Remote Pump Control Verification (3865)

3.9.5.1 ENTER and UP/DN key verification; Load test IV Set in 3850 Pump. With Remote Rate set to 100 and VTBI set to 10.

3.9.5.2 Start Control and Green Run Led Verification; With Test IV Set loaded in 3860+ Pump, Rate set to 100, VTBI set to 10, and test Pump displaying "Ready To Start". Press START/STOP Channel A on Remote and verify 3860+ Pump starts pumping and Green run LED flashes on Remote.

3.9.5.3 Alarm Led Verification; With Pump running as described above, occlude inlet on Pump and verify the following:

1. Pump stops
2. Inlet Occluded flashes in the upper portion of the screen
3. Audio alarm sounds
4. Red bar alarm LEDs flash

3.9.5.4 ALARM SILENCE Key Verification; Press the Alarm Silence key and verify the audio alarm sound is silenced.

3.9.5.5 CANCEL Key Verification; With Pump stopped and red bar alarm LED flashing, press the CANCEL Key and verify Alarm LED stops flashing and "Ready to Start" flashes at the bottom of the screen.

3.9.5.6 MENU Key and Alarm Sound Adjustment Verification; Press the MENU Key, then press the Alarm Volume soft key, and using the Up/Dn arrow keys, verify the alarm volume can be raised, lowered and saved (by pressing the ENTER key) to the appropriate setting.

3.9.6 Remaining Soft Key Verification

With Key Lock enabled in the 3860+ Pump Service Menu, press the MENU Key and verify the following:

3.9.6.1 Verify pressing (F1) soft key "Dose Rate Calculation" displays the Dose Rate Menu (press CANCEL).

3.9.6.2 Verify pressing (F3) soft key "KVO Rate" displays the KVO Rate menu (press CANCEL).

3.9.6.3 Verify pressing (F4) soft key "Occlusion Limit" displays the Occlusion Limit Menu (press CANCEL).

3.9.6.4 Verify pressing (F5) sof key "Lock Keys" (twice) returns to normal display and all keys except MENU and OFF (0) are locked. Press menu and (F5) soft key to "Unlock Keys".

3.9.6.5 Verify pressing (F6) soft key "NEXT MENU" displays the next menu with (F3) soft key "Set Comm Channel" selection (press CAnCEL).

3.9.7 BATTERY CHARGE and Burn-In Verification (3865)

Install a new uncharged Battery (1133) and power on the 3865 while holding down the "CANCEL" key.

3.9.7.1 Press the (F2) soft key and verify the following Battery Status: State of Charge (%) xxx [0 to 2] Term. Voltage (V) xx.xxx [15 to 16.8].

Cell 1 x.xxx [3.8 to 4.25]

Cell 2 x.xxx [3.8 to 4.25]

Cell 3 x.xxx [3.8 to 4.25]

Cell 4 x.xxx [3.8 to 4.25]

Current (ma) xxx [+20 or greater (Note for later reference)]

cycle count x [0]

S/N (Verify serial number matches serial number on battery)

3.9.7.2 Record "Start Burn-in" time and leave 3865 on in this mode for 12 hours.

3.9.7.3 After 12 hours, record Burn-in stop time. Verify if Battery is fully charged and Battery Term. Voltage (V) in Battery Status display is 16.84 +0.03/-0.

SECTION 4
PRINCIPLES OF OPERATION

4.0 PRINCIPLES OF OPERATION

4.1 Introduction

The operational principles upon which the Iradimed 3860+ MR IV pump and its accessory parts are based is presented in the following sub-sections. The presentation format compliments the maintenance and troubleshooting instructions found in their associated sections of this manual. Reference should be made to the system block diagrams, schematics, mechanical drawings and parts lists, as one follows the operating principles description herein. The theory behind the fundamental operating principles is also given, however it is assumed that users of this information are generally familiar with the operation and maintenance of linear peristaltic infusion pumps.

Generally, the presentation is broken into mechanical and electronic subsections. Mechanical operation and componentry are discussed first. Electronic circuitry and theory of operation are described second. The electronics discussion can better understood if one reviews the block diagrams and schematics in parallel with the text. It must be kept in mind that this equipment is software controlled, and so much of the operation is not obvious from the drawings alone. In fact the 3860+ MR IV pump has two processors with much of the safety and control based upon these processors 'watching' the operation of the other.

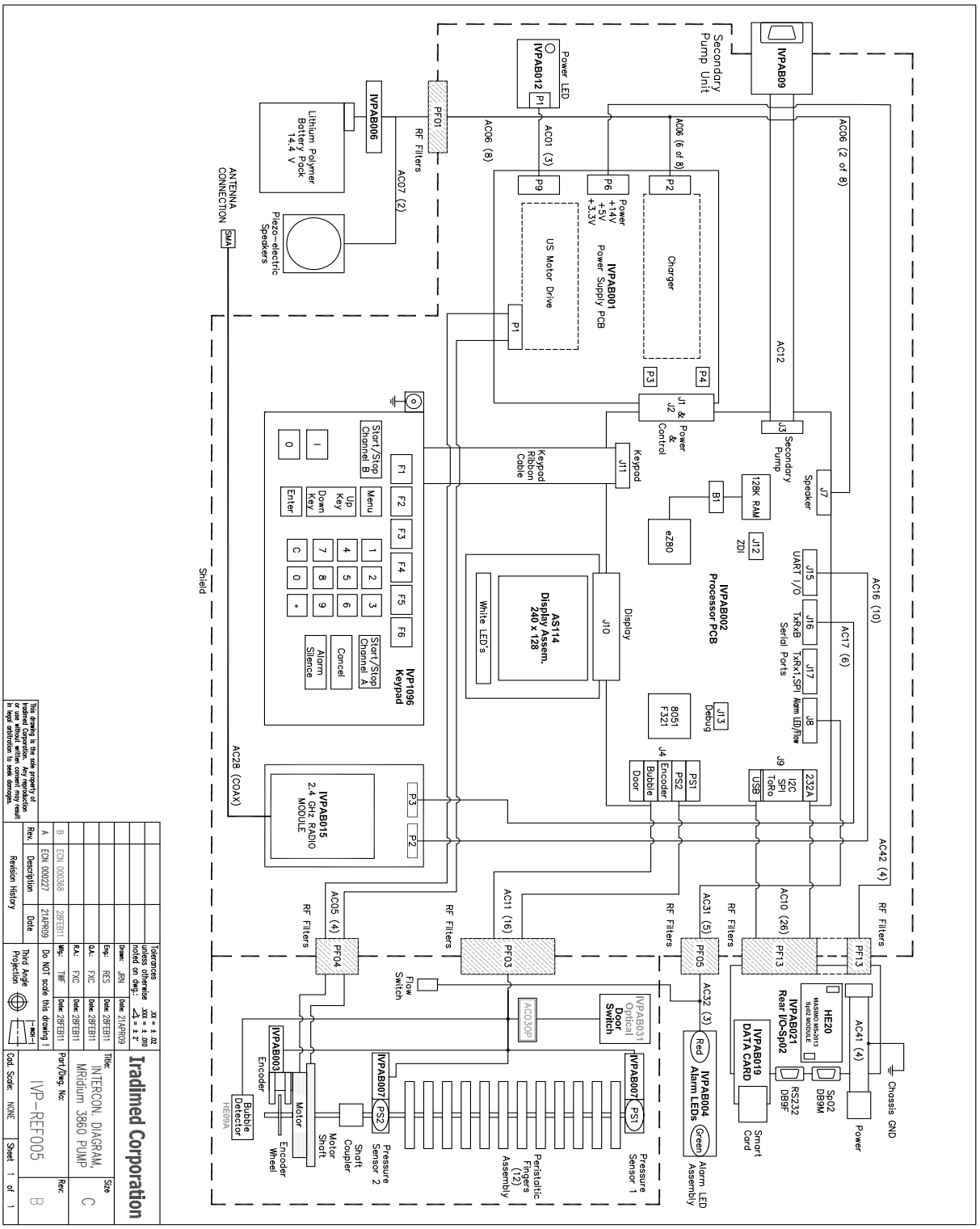
4.2 Mechanical Operation

Though complete direct observation of the mechanical operation which occurs as the pump runs is not possible with a fully assembled unit, detailed drawings of the mechanical assembly are included below, which along with the following text, should provide a thorough understanding of the pumping operation.

It is assumed that the reader has previously obtained an understanding of the 3860+'s basic user operation and setup. A general familiarity of the operation of linear peristaltic mechanisms and the operation of the 3860 is a pre-requisite.

4.2.1 Physical Description

Reviewing the block diagram (**See Figure 4-1**) and overall chassis assembly (**See Figure 4-2**), it can be seen that the 3860 is housed in a multi-chambered cast aluminum chassis. Two main chambers exist, one for the RF 'noisy' electronics (left side) and the other for the mechanical pump assembly and sensors or the right side. Electrical connections pass through a separating center wall via RF feed through filter plates (PFxx). As the 3860+ has been specifically designed to operate in close proximity to the high magnetic fields and extremely RF sensitive environment of Magnetic Resonance Imaging 'Scanners', much of design will reflect the attention given to reducing magnetic hazards and RF susceptibility in addition to IV fluid delivery.



This drawing is the sole property of Iradimed Corporation. Any reproduction or use without written consent may result in legal obligation to seek damages.

Revision History			
Rev.	Description	Date	
A	ECN 000227	21APR09	
B	ECN 000368	28FEB11	

Tolerances unless otherwise indicated on drawing: XX = ± .02 XXX = ± .010 ∠ = ± 2°

Third Angle Projection

Do NOT scale this drawing !

Drawn:	JRN
Eng:	RES
Q.A.:	FXC
Mfg:	TWF
Date:	21APR09
Date:	28FEB11
Date:	28FEB11
Date:	28FEB11
Date:	28FEB11

Iradimed Corporation

Title: INTERCON. DIAGRAM, MRIdium 3860 PUMP

Size: C

Part/Dwg. No: IVP-REF005

Rev: B

Cod. Scale: NONE

Sheet 1 of 1

Figure 4-1.

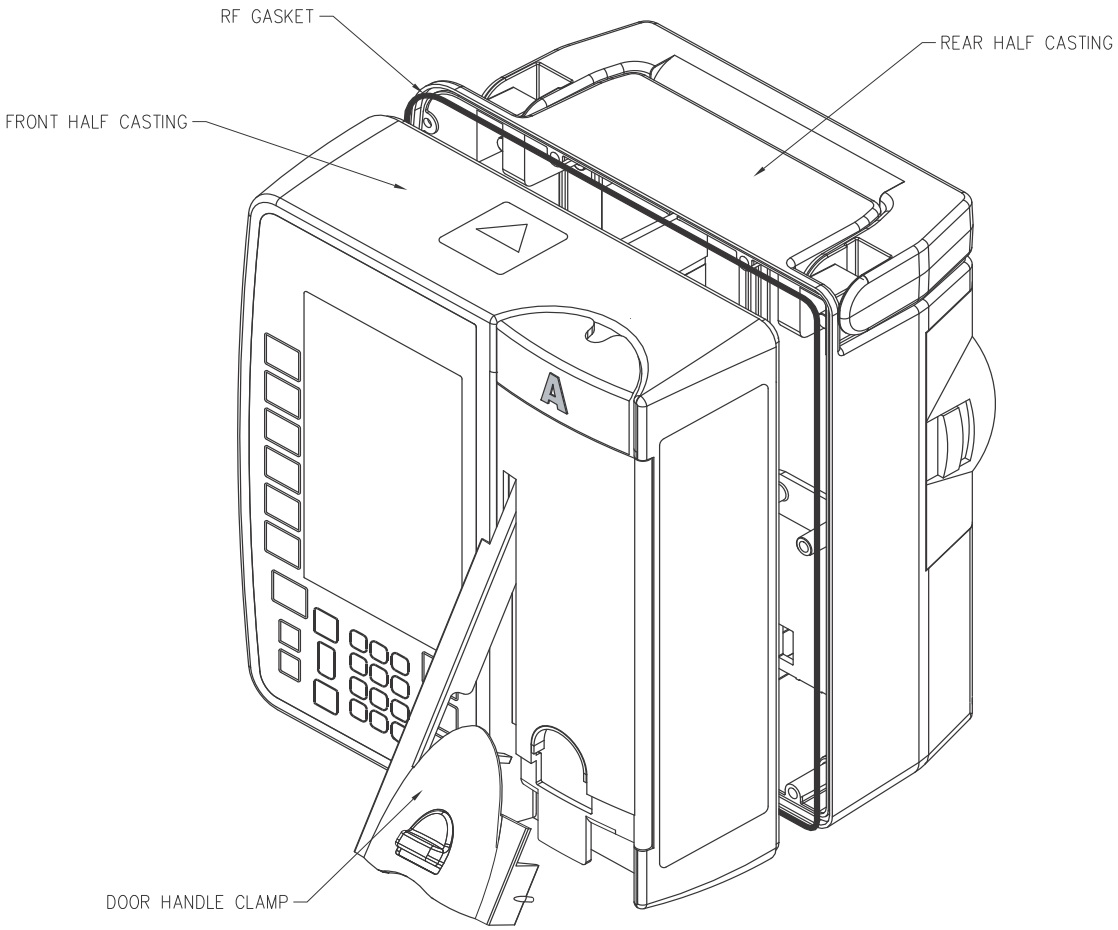


Figure 4-2.

Generally, all the RF noise producing electronics are located on the display side of the chassis. The Pump side is designed with non-RF producing 'analog' or very slow digital electronics along with the non-magnetic ultrasonic motor. The surround of the chassis contains RF gasket material which provides both RF tight and drip proof seal keeping RF noise from getting out or in. Careful attention to this gasket must be given when opening and re-closing the case to maintain the RF and moisture sealing integrity of the unit.

4.2.2 Pumping Mechanism

The linear peristaltic pumping mechanism assembly consists of three principle subassemblies shown in Figure 4.3: the non-magnetic ultrasonic motor, the camshaft/pumping finger housing and the 1000ppr optical rotary encoder. The motor drive shaft is connected to the camshaft via brass hex coupling. The encoder wheel of the position/ speed sensing optical encoder is connected directly to the rear of the motor shaft. The camshaft is configured with 12 vertically staged cam lobes on a hex brass shaft. The eccentric axis of each lobe is offset 30° counterclockwise from the lobe directly above. This positioning provides full forward travel for each pumping finger sequentially from top to bottom during each counterclockwise (when viewed from below) revolution of the camshaft/motor.

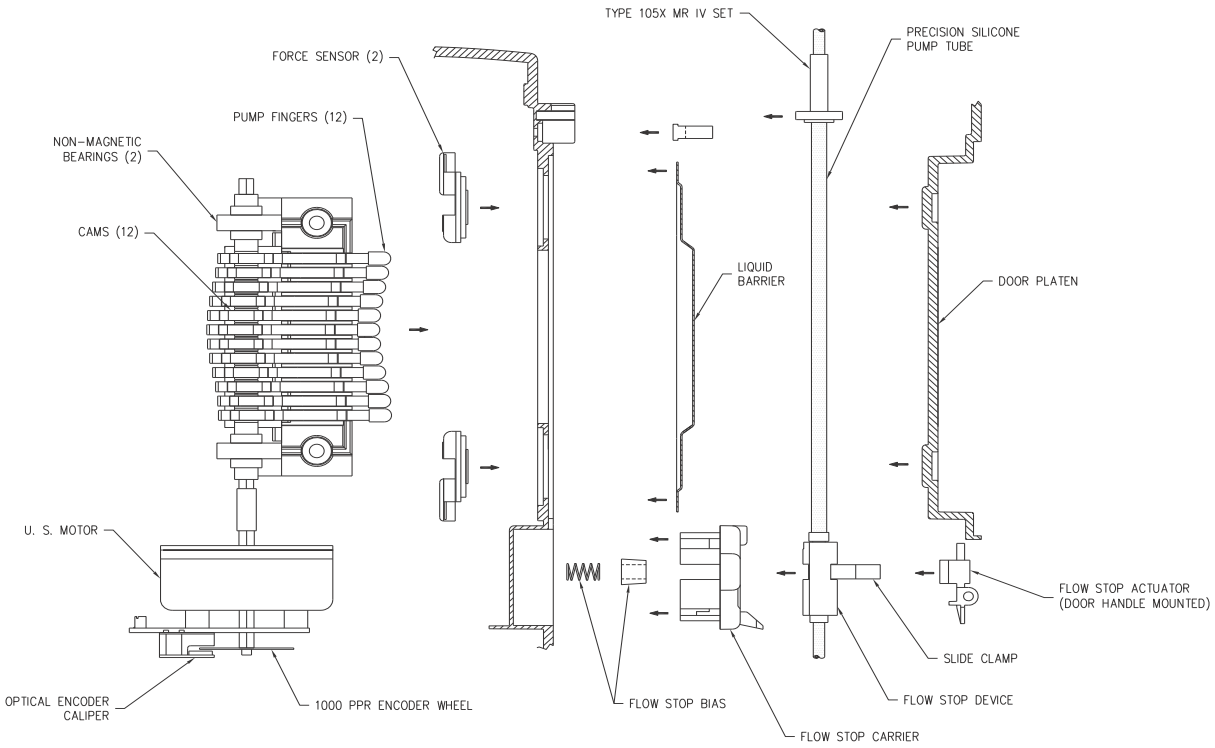


Figure 4-3.

4.2.3 Force sensors (Pressure Transducer)

Pressures within the IV set tubing are sensed via tubing wall force exerted upon the face of two semiconductor force sensors. One located directly above the pump mechanism for inlet pressure/occlusion sensing, and the other below, for patient side fluid pressure sensing. These sensors must be zeroed and span calibrated with IV set tubing in place. From the drawing, it can be seen that the door platen has two 'raised 'button' areas which flatten the silicone section of 105x MR IV sets, over the sensing face of each force sensor. As pressure changes within the tubing, the associated force change is transduced and electrically sent to the 12 bit A/D converter of the master processor. Zero and span cal information, previously obtained via the calibration procedure, are recalled from flash memory and applied to the A/D values resulting in a calibrated output value indicating the actual pressure within the tubing.

This pressure information is used to determine the inlet and outlet fluid conditions such as, inlet occlusion or patient side high fluid pressures.

4.2.4 Mechanical Functional Operation

In the Normal operating mode (not service mode), the 3860+ MR IV pump is initialized when the front panel POWER ON "(I)" control is actuated. After a brief power on self test of the internal memory (flash and battery backed RAM), the pumping mechanism will advance to a known 'home' position when the door is opened. Each time the door is opened internal tests of the motor movement and encoder operation are conducted. The force sensors are also tested for return to initial zero calibration settings. Force sensor signals are used in conjunction with the door closed signal, to determine that an IV set has been loaded. Infusion parameters may be programmed and the START control actuated after successful loading of an IV set, as verified buy door close and appropriate tubing pressure feedback.

The Ultrasonic motor is directly coupled to the camshaft which actuates the pumping fingers. Motor speed is variable and it is driven at a speed proportional to the rate programmed for the infusion. The encoder provides both an index pulse once each full rotation of the mechanism and minor position signals, 1000 per each revolution (each 0.36 degrees). The motor control processor AB02-U6, issues motor run pulses to the analog US motor driver chip, AB01-U2 and watches for encoder pulses (ticks) indicating the mechanism is in motion. Depending upon the user programmed rate, the motor is moved 2 to 20 pulses (ticks) per 'on' time interval. This translates to a rotational arc of 0.72 to 7.2 degrees of step like motion per motor run pulse from U6.

Volume to be infused (VTBI) is a function of the total accumulated number 'ticks' caused by motor run pulses from U6. And flow rate a function of the rate at which motor run pulses are issued. The encoder wheel attached to the motor shaft and its optical sensing caliper mounted on the back shell of the motor, provides the electronic control system with camshaft's position and speed of rotation. Encoder data is fed back to both processors where each independently validate proper motor/camshaft movement to verify rate and volume accuracy. Should the processors disagree upon the motors movement, a critical alarm is given and all pumping action stops. The motor kill signal is wired so that either processor may directly shut down the motor drive power FET's directly via AB01-U5 and U6.

Upon access door opening, the processors attempt to advance the pump block and motor to an initial starting position where the fingers are in a known location ready to begin a new pump cycle. Tests are done during this process to assure the mechanism moves properly and at correct maximum speed to its initial position. The encoder signals are counted and index pulse validated as well. With this test passed, the unit is ready to load an IV set.

When an Iradimed 105x type IV administration set is installed and the access door is closed and latched, the set's flowstop is opened by action of the flowstop actuator pressing the slide clamp into the flowstop bias arm. At the same time, the silicone pumping tube segment is compressed by one fully extended pump finger and the door platen, preventing any free flow. Pumping begins following actuation of the START 'A' or 'B' control button. The motor controller and US motor, rotate the camshaft at a rate determined by the programmed infusion

rate. During each pump cycle (one rotation), encoder pulses are accumulated and timed. Timing is not held steady for each given flow rate, but rather 'modulated' through a series of various speeds which linearize the inherent non-linearity of peristaltic pumping mechanisms and produce a uniform rate of fluid flow throughout each pumping cycle. The start position and duration of each of these linearizing speeds is held in flash memory of motor controller U6. This position is found during factory calibration with the pump connected to a high accuracy calibrated scale while the delivery profile at 1 ml/Hr is studied by internal calibration software. Anytime the mechanical alignment of the encoder wheel relative to the pumping finger position is changed or suspect (pump block or motor replaced), this calibration process must be performed.

The sequential extension and retraction of the pumping fingers from top to bottom results in a downward moving compression zone within the administration set's pumping segment (see Figure 4-3) creates positive pressure on the outlet side (distal end) of the tubing set. Resilience of the silicone pumping segment tube causes it to return to its cylindrical shape as each of the pumping fingers recede from the extended position. This reshaping creates a vacuum in the proximal tubing and draws fluid from the IV solution container to refill the tubing. This peristaltic-like action along with the modulation of speed each results in a smooth, controlled flow of IV solution from the fluid source to the patient.

4.3 Electronic Operation

Electronic functionality and inter-relationships are discussed below. Utilize the block diagram of **Figure 4-1** along with the schematics for the various PCB's discussed for a complete view of the electronic operation.

4.3.1 Electronics Functional Description

The MRidium 3860+ MR IV pump's electronics are micro processor based. There are two processors working together to accomplish this control and to check one another. providing a high degree of system safety and control.

The master processor is a Zilog eZ80 type (U3) with on board 8KB RAM, 128KB Flash, two serial UART's, SPI, and I2C communications along with Real time clock and general purpose I/O. In addition to these on board resources there is an external 128KB of battery backed RAM and 512KB of flash for extended program storage as well as 12 bit A/D for gathering analog signal data. The RAM is used to store over 5000 operations history records for serial download from within the service mode. Operating at 22MHz, the eZ80 communicates with the motor control processor and rear panel Data Flash memory socket via the SPI and with the smart battery gas gauge vi the I2C port. The UART communications are routed to the rear panel RS232 I/O port and the internal 2.4GHz remote control radio sub-system (optional equipment).

The second processor is considered the 'motor control' processor and is an 8051 type operating at 12MHz, shown as U6 on the IVPAB002 schematic. Communication with the master is via the SPI serial buss. It outputs a motor run command to the custom analog IC, AB001-U2, to cause the motor to turn. Each processor receives and counts encoder

pulses or ticks, and performs an independent check for proper motor speed. The index is also watched by U6, so that proper mechanical positioning is maintained for the correct application of the speed modulation profile which linearizes the flow characteristic of the pump.

The master translates user input flow rate requirements into a time expected between each encoder pulse, or Master Tick Time. This is transmitted to the motor control processor U6, every one second. Additionally, the master collects the tubing pressure data via a 12 bit A/D converter. Inlet and outlet pressures are averaged and used to compensate the Master Tick Time so as to maintain accurate flow under conditions of low or high inlet and outlet fluid pressure. New and continuously compensated, Master Tick Time values are transmitted to U6 each second. Each processor has a safety timer running to assure that this communication proceeds as planned without interruption. Should either processor find a breach of this communication, the pumping action is stopped and motor kill asserted. Both processors can drive the alarm system in a wired fashion for both alarm light and sound.

The master processor also utilizes the pressure data to determine out of range conditions on either the inlet or outlet side of the pump. The inlet pressure in monitored for negative delta from an initial average created just after door closure. If this pressure drops beyond a preset amount, the Inlet Occlusion alarm will be triggered.

Outlet pressure is compared to the Occlusion Pressure limit user set in the Menu selection for this limit. Should pressure rise to this limit the Patient Occlusion alarm will be activated.

4.3.2 Power Supply / Motor Driver Functional Operation

The function of each major subsection shall be discussed below. Reference to the appropriate schematic, IVPAB001, will help with the understanding.

4.3.2.1 Power Good and RAW power enable

DC power from the AC adapter (PN 1120) or the Li polymer battery is level detected and switched to the RAW power line by a BQ24702 Li battery charger and power monitor IC shown as U1 on the AB001. When the DC input at P6 reaches 16.5V, Q10 will be turned on passing this power on to the RAW power rail. Otherwise, battery voltage above 10.5V at P2 will be chosen via Q8 to supply RAM power. RAW power is applied to IR1 an LT3431 switching regulator, the power on/off circuits and the Side Car RAW power connector.

4.3.2.2 Power On/Power Off Subsystem

Power on is controlled by pulling R31 low via the front panel power on button. This low going signal pulls charge from C17 and the gate of Q7, turning Q7 off. This allows the drain of Q7 to rise at the rate determined by R23 and C11 until the shut down threshold at pin 15 of IR1 is surpassed. This allows IR1 to start up the 10V regulated power rail. As the 10 volts rises, Q5 will turn on and hold Q7 cutoff so that the ON button can be released.

Power off involves pulling the shutdown line, pin 15 of IR1 low through R29, and draining the hold on charge from C18 via D21. The low going off signal is generated with a time delay on the AB002 processor board using U20 and U21 along with the charge on C82. This delay requires that the OFF button be held down approximately 2 seconds to turn the unit off.

4.3.2.3 11V Power Supply

The 11 volt regulated supply, turned on as described above, is a high frequency switching regulator using an air core 10 uH inductor and internal 3A switch. R26 and R27 set the supply to output 11 volts. This supply is used directly by the motor driver IC U2 and power FETs, Q1-4 to produce the 45kHz ultrasonic drive power for the US motor. It is also the power supply for the audio power amp. The 11volts directly feeds the 5 volt switching regulator of IR2 which in turn powers a linear 3.3 V regulator, IR3.

4.3.2.4 Logic 3.3V and 5V DC Power Supply Subsystem

IR2 is a LT1767 fixed 5 volt output 1A switching regulator powered directly from the 11 volts from IR1 once it starts up. This supply is used by the LCD display, portions of the US motor driver and directly powers the LT 1767 linear 3.3 volt logic supply.

4.3.2.5 Battery Charger Subsystem

All battery charger functions are controlled by U1, a BQ24702 Li charger IC suitable for charging up to 4 cells in series. The battery also contains a gas gauge and charge monitor IC which limits the charge voltage and currents allowable into the battery pack. Smart circuits in the battery pack also will shut off the battery output should any over current event be sensed. In this case the pack will not delivery power until it is placed back on proper charge from U1. The MRidium Li battery pack is a 4S4P design producing 14.8 V with a 6 amp hour capacity. Output is limited to 3 Amps.

U1 will sense the battery voltage, and if too low, supply only a small trickle charge limited by R20 until the battery ‘floats’ up to about 10 volts. There after a 300kHz switching charge current of 1.5A is delivered via Q9 and TX1, to the battery. Charge is complete once the pack reaches 16.85 V. This terminating voltage is set by R89. R19 supplies charge current feed back to the circuits within U1. R5 is used to sense the current draw from the AC power adapter. This is limited to 2A as the charger is rated for 19V at 2A. The charger chip, U1, will ‘steer’ power to the RAW power buss to power the pump with priority over the charging current. As the pump (and Side Car) may require up to the full 2A available from the AC adapter, Q9 will be PWM towards off as current is needed on the RAW power buss. In this way, the pump can fully operate, delivering any desired IV flow rate, even if the battery is fully depleted. With U1 ‘steering’ current to the battery only so long as the pump gets all it requires.

4.3.2.6 US Motor Driver

The IR3C21N IC shown as U2, is a custom analog integrated circuit which generates the approximately 45KHz sin and cos drive for powering the US motor. The motor run command from U6 on the AB002 turns off Q6 and enables U2 at pin 1, via U3. R57 sets the oscillator frequency and R41 controls the amount of feedback from the motor once it begins turning. R53 charging C22 creates a turn on frequency sweep to the oscillator through R46. This ultrasonic motor is a multi-phasic high power type which requires a slightly higher drive frequency to start, then a lower running frequency. The charge on C22 provides this startup frequency change.

Once the motor begins turning, voltage will appear on the feedback terminal (P1 -3) which is rectified and passed back into a control loop at pin 6 of U2. As the load on the motor changes, the feedback will waiver and self adjust the drive frequency smoothing speed fluctuations. The amount of feedback set by R41, controls the stabilized top speed of the motor, though this is somewhat interactive with the setting of R57.

The outputs on pins 15 -18 of U2 pass to special high speed FET gate drivers, U5 and U6. These drivers provide a very fast, level shifted drive into the power FET's, Q1-4, for high efficiency operation. These drivers also have a shutdown input which the safety logic of both processors can assert to kill motor operation should a system fault be detected. The FET's switch the 10 volt supply though two special air core transformers to produce the 100 V RMS sin and cos ultrasonic drive to the motor.

4.3.3 Processor Assembly

Use the schematic diagram of the IVPAB002 to follow with the functional overview below.

4.3.3.1 System Reset Circuit

The LTC694 reset circuit shown as U1, provides power on reset, power fail detection, and battery backup RAM power and CE control. Power fail threshold is set by R1 and R2, this causes a power fail interrupt to U3-52. Upon power fail the battery B1 voltage is switched to maintain power to the RAM (U4) and real time clock through U3-60. U1 also blocks chip select activity from reaching the RAM by gating off the CE at pin 12 and 13.

4.3.3.2 Master Processor

Upon power up, once the 3.3V line and PFI voltage from the 5 volt line are seen to be 'good,' master system reset is released and the processors begin operation.

The MRidium 3860/3860+ is based upon a multi-processor design, with a main processor for user interface, system wide functions, dose rate calculations and rate/volume motor controller computations and communications. This main processor, a Zilog eZ80 (U3), also watches the function of the motor control processor(s). Motor control processors, 8051 based, are located on the main processor (IVPAB002 – U6) for pump channel A, and within the SideCar, for channel B.

The eZ80 contains 128KB of flash for storage of main system program code. An additional 512KB of outboard flash holds additional feature code, such as remote control and export language data. System code is updated via 'Data Flash' memory cards inserted in the memory slot on the back right side of the pump. This memory is controlled and read/written via the eZ80 SPI communications buss. A small 'loader' resides in the internal flash providing basic code for loading the larger main code body via SPI, from the data flash socket. A small loader in the motor controller (U6) accepts download from eZ80 and writes motor controller code into the 8051 internal flash.

Once power on reset has occurred, the eZ80, running at 22MHz, starts up and initializes both its internal and external I/O devices. These include real time clock, counter timers, GPIO lines, SPI, I2C, internal and external (U8) UARTs, A/D (U5), and LCD display. Once these basic hardware units are initialized, the main software process begins. Keypad is continually scanned under 60 Hz interrupt driven timer. Display output is 8 bit parallel write to J10 via data buss buffer U7.

On board (U6) and external (SideCar) motor controllers communicate via SPI buss and unique slave select lines, U9-12/15. The eZ80 directly monitors all pressure sensors, via A/D U5, both IV set door switches and motor encoder/ feedback signals. The eZ80 performs the pressure limit, door open and overall watch dog safety processing.

When user rate and volume data are input via the key pad, the eZ80 converts these inputs to a time between each encoder tick, or the time to move the motor 0.36 degrees. This value and the total VTBI as a total run time value, are transmitted to the motor controller for channel A or B. The motor controllers use this information to cause the pump unit to deliver the programmed rate and volume. Flow rate is compensated for changes in inlet and outlet pressures to maintain accuracy. New tick time values are sent each second to the motor controllers.

During all times, the eZ80 monitors the encoder output from both the internal pump encoder and the SideCar B pump encoder, if it is attached. Since the eZ80 'knows' the desired programmed rate/volume and how much the motor should be run to achieve this target as well as when the motor should be turning, the master processor serves as a redundant

system, checking the proper function of the motor controller(s). Should the eZ80 find encoder ticks (indicating motor movement) arriving at the wrong time or rate, the motor controllers will be issued a stop command and the motor kill line asserted, along with a critical error message and alarm.

4.3.3.3 Motor Control Processor(s)

The motor controllers are Silicon Labs C8051F320 8 bit single chip processors with internal clock oscillator and power on reset circuits. These processors run entirely independent from the master processor. Once the internal power good and reset criteria are met, these processors initialize and prepare to receive commands from the master processor.

The 8051's receive time data indicative of the rate and volume programmed by the user, as described above. Internal program code issues motor run pulses to the US motor driver circuit on the IVPAB001. Encoder pulses for each .36 degrees of motor/pump rotation are accumulated and timed. The algorithm keeps account of small deviations between desired tick time and actual, extending or retarding motor run pulses to overcome short term speed/flow errors. However, should the encoder pulses accumulated indicate the motor speed errors beyond preset limit thresholds, the pump will stop and master processor issued a critical error code.

4.3.3.4 Audio Subsystem

The audio for alarm tones is generated by wave shape filtering and power amplifying clocking signals from either the eZ80 (U3) or U6. These tone clock signals are summed at R37. U10 is a digital pot controlled by U6. This 50K digital pot has 32 taps settable by front panel controls within the MENU option. Its output is filtered by the poles of U11. U12 is a dual channel audio power amp in bridge tied load (BTL) configuration. Operating on the 10 volt supply and tied as BTL, this amp can output 20 V P-P to drive two peizo speakers for proper (loud) operation in high magnetic fields.

4.4 Air-In-Line Detector

The air-in-line detection system includes two piezo-electric crystals and a signal processing circuit. The PE crystals and acoustic lenses are bonded into recesses in the detector housing. The signal processing circuit is part of the bubble detector printed circuit board mounted directly behind the detector housing in a well cast into the chassis. Ultrasonic sensing is used for air-in-line detection. Ultrasonic signal transmission (acoustic impedance) through IV compatible solutions falls within a very discrete range which is easily discernable from passage through air.

The air-in-line detector is located below the pumping mechanism and checks the integrity of the fluid column entering the patient side (distal portion) of the tubing set. The acoustic lenses and installed tubing set provide a coupling path for the continuous wave ultrasonic transmission to travel from the transmitting to the receiving crystal. When the tubing contains an IV solution, the acoustic impedance is low and maximum energy is coupled to the

receiving element which generates a voltage signal that is proportional in amplitude and frequency to the coupled energy. If an air bolus is interposed between the lenses, the acoustic impedance is significantly increased as the acoustic wave is reflected by the liquid-air interface. The energy received is reduced and the voltage output is commensurately reduced. This signal differentiation combined with the instruments programmed delivery rate is used to measure the volume of the air bolus.

By counting time from the onset of air detect and comparing this with the rate at which fluid/air is moving though the tube due to the programmed rate. The size of the air buuble can be determined. The 3850 will alarm when it measures an air bubble of 100uL.

4.5 Door Sensor

The door closure is sensed by a switch mounted behind the door in the lower outside corner *(in 3860 Pumps (Serial Number IR60100153 and higher) and 3861 Sidecar (Serial Number IR61100110 and higher) this switch is replaced by an Optic Sensor IVPAB031*). A Hard Rubber actuating pin on the inside of the door clamp engages the switch *(or Optic Sensor)* when latched in the closed position. Door open will trigger an alarm and pump shut down if detected during pumping. The sense of an open condition advances the mechanism to its programmed starting point and conducts a test of the motor and encoder system as well as pressure sensor auto zero. Upon door close, a tubing pressure offset is checked verifying proper IV set placement and the pump readied for starting.

4.6 Flow Switch

On 3860 pumps serial number 120 and above a Free-Flow Detector Switch was installed. Reference drawing AF3860 or AF3860+ Sheet 1 of 4, Detail A for location of IVPAB016 Flow Stop Switch assembly.

When the door is closed the silicone pumping tube segment is compressed by one fully extended pump finger and the door platen, preventing any free flow. When the door is opened a puller located in the door clamp handle pulls the pinch clamp in the IV set to prevent flow. System software monitors the Flow Stop switch and Door switch and if the Flow Stop switch is not open within .75 second of detecting the Door Switch open a Check Door Alarm will be activated.

4.7 Display Subsystem

The display is a custom designed non-magnetic 240 X 128 graphic type FSTN LCD with 1330 type controller and LED backlight. The display is powered from the 5 volt rail. A special RF shield screen mesh is mounted over the display and held by RF 'finger' gasket material around its entire circumference. Should the display be removed, this shield will need to be carefully replaced.

4.8 Communications Interface and Signal Definitions

Signal Name	Pin Number	Direction	Definition
GND (Ground)	*1*	Host	NC
TX (Transmit Data)	*2*	3860 to Host	Serial data transmitted to host computer from MRidium 3860
RX (Receive Data)	*3*	Host to 3860	Serial data transmitted to MRidium from host computer.
RTS (Request to Send)	*7*	3860 to Host	When asserted, RTS indicates to the host computer that the 3860 has information to transmit. Can be used to tell the host computer to wait
CTS (Clear to Send)	*6*	Host to 3860	Asserted by the host computer to enable the 3850 to transmit data.
DSR (Data Set Ready)			
Signal Ground	*5*	3860 to Host	Common signal return to TxD, RxD, DTR, DSR, RTS and CTS.
DTR (Data Terminal Ready)			
Not Connected	*9*		

NOTE

Maximum leakage current to chassis ground from connected peripheral equipment must-not exceed 400uA.

4.9 Critical Error / Service Codes

The following table defines the critical error codes of pump malfunctions:

Alarm #	Code	Action Description	Details of Description
1	23	Pump Malfunction - Master / Slave communications failure	Channel A
2	23	Pump Malfunction - Watchdog timeout	
3	23	Pump Malfunction - Motor control processor watchdog timeout	Channel A
4	23	Pump Malfunction - Nonmaskable interrupt	
5	23	Pump Malfunction - ROM checksum error	
101	23	Pump Malfunction - Master / Slave communications failure	Channel B
103	23	Pump Malfunction - Motor control processor watchdog timeout	Channel B
129	23	Pump Malfunction - Slave processor did not see encoder index while seeking starting index mark	Channel A
130	23	Pump Malfunction - Motor is rotating too slow.	Channel A
132	23	Pump Malfunction - Starting index mark found in wrong position relative to minor index marks.	Channel A
134	23	Pump Malfunction - Should have seen a minor index mark and has not.	Channel A

135	23	Pump Malfunction - Should have seen a minor index mark while the motor is not running and has not seen a minor index mark.	Channel A
136	23	Pump Malfunction - Slave processor did not see encoder index during normal operation	Channel A
229	23	Pump Malfunction - Slave processor did not see encoder index while seeking starting index mark	Channel B
230	23	Pump Malfunction - Motor is rotating too slow.	Channel B
232	23	Pump Malfunction - Starting index mark found in wrong position relative to minor index marks.	Channel B
234	23	Pump Malfunction - Should have seen a minor index mark and has not.	Channel B
235	23	Pump Malfunction - Should have seen a minor index mark while the motor is not running and has not seen a minor index mark.	Channel B
236	23	Pump Malfunction - Slave processor did not see encoder index during normal operation	Channel B
1000	23	Pump Malfunction - shaft revolution occurred in less than the required amount of time	Channel A
1001	23	Pump Malfunction - Shaft revolution should have occurred but did not.	Channel A
1002	23	Pump Malfunction - Shaft revolution timeout error	Channel A
1003	23	Pump Malfunction - Shaft should not be turning but it is turning.	Channel A
1100	23	Pump Malfunction - shaft revolution occurred in less than the required amount of time	Channel B
1101	23	Pump Malfunction - Shaft revolution should have occurred but did not.	Channel B
1102	23	Pump Malfunction - Shaft revolution timeout error	Channel B
1103	23	Pump Malfunction - Shaft should not be turning but it is turning.	Channel B